PSJ3

Exhibit 674C

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
275 EAST MAIN STREET HS2GW-B
FRANKFORT 40621-0001

Department for Public Health
Drug Enforcement & Professional Practices Branch

[redacted], MD
[redacted]
Louisville, KY 40204

AT: Frankfort, KY

BY: Danna Droz
Branch Manager

DATE: May 15, 2002

The Kentucky Board of Medical Licensure requested the assistance of the Drug Enforcement Branch in its investigation of Dr. [redacted]. Specifically it was requested that Dr. [redacted]'s prescribing patterns be analyzed and patients identified for whom inappropriate prescribing may have occurred.

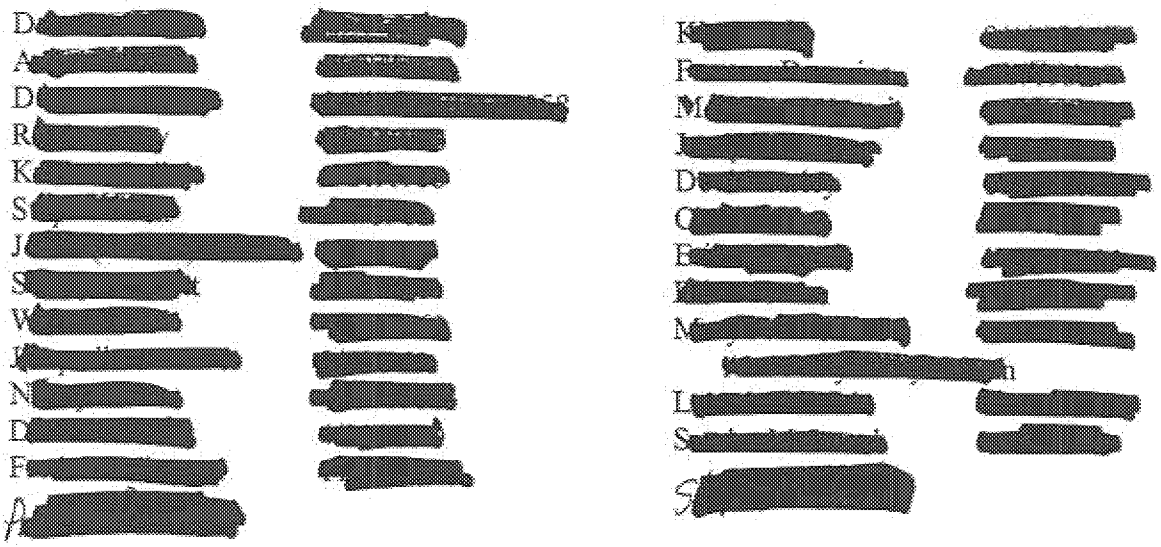
After reviewing the KASPER records for 7/1/2001 through 8/31/2002, I have several concerns:

- Long-term use of two or more controlled substances, sometimes in unusual combinations;
- Combinations of controlled substances favored by persons who abuse or divert controlled substances;
- Patients using multiple pharmacies;
- Patients driving long distances (Prestonsburg, Salyersville, Monticello, Bowling Green, & Georgetown) to see this physician;
- Long term use of acetaminophen-containing compounds at near toxic levels, especially in a patient who is 70 years old; and
- Patients getting refills from 2 prescriptions at the same time which could indicate inadequate record keeping by the physician;

Please note that these conclusions were reached and patient names selected after review of only one-third of the records. If more patient names are required, dozens can be easily provided.

CONCLUSION: There exists sufficient indication of inappropriate prescribing to warrant further investigation.

RECOMMENDATION: It is recommended that a Medical Board consultant review the following patient records:



CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
275 EAST MAIN STREET HS2GW-B
FRANKFORT 40621-0001

DEPARTMENT FOR PUBLIC HEALTH
Drug Enforcement & Professional Practices Branch

COPY

[redacted], MD
[redacted]
Bellevue, KY 41073

AT: Frankfort, KY

BY: Danna E. Droz, RPh, JD, Manager
Drug Enforcement and Professional Practices Branch

DATE: December 10, 2001

The Kentucky Board of Medical Licensure requested the assistance of the Drug Enforcement Branch in its investigation of Dr. [redacted]. Specifically it was requested that Dr. [redacted]'s prescribing patterns be analyzed and patients identified for whom inappropriate prescribing may have occurred.

After reviewing the KASPER records requested by Ms. Prater, several concerns became apparent:

- Long-term use of one or more controlled substances;
- Combinations of controlled substances favored by persons who abuse or divert controlled substances;
- Patients using multiple pharmacies;
- All patients receiving small quantities and no refills for an extended period of time; or
- Long-term use of a controlled substance for which short-term use is generally indicated.

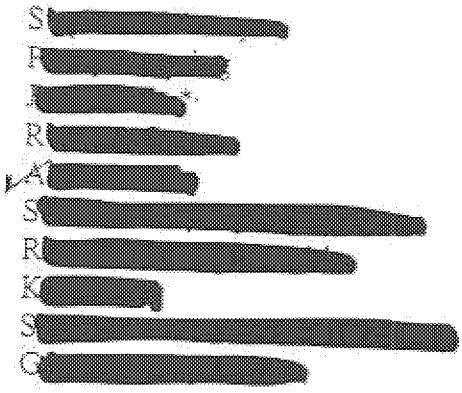
The following patient records should be reviewed to determine whether Dr. [redacted] provided appropriate medical care. It should be noted that Dr. [redacted] and Dr. [redacted] treat many of the same patients. It appears that an office visit is required every two weeks in order to obtain further quantities of a controlled substance. In every instance that I checked, any gaps in the prescribing patterns by Dr. [redacted] were filled by Dr. [redacted] Therefore, in selecting patient names, I attempted to select those for whom Dr. [redacted] was the primary treating physician so as not to confuse the issues of prescribing by Dr. [redacted] with prescribing by Dr. [redacted] (Exceptions are noted by * and were included because of extensive prescribing by Dr. [redacted])

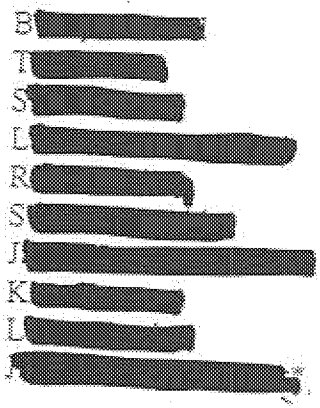
C[redacted]
M[redacted]
T[redacted]*

C[redacted]
S[redacted]*
E[redacted]

EDUCATION PAYS

"An Equal Opportunity Employer M/F/H"





This office has also received several complaints about excessive prescribing of controlled substances by Dr. [redacted]. One such complaint alleges that 90% of the prescriptions from his office are for controlled substances.

RECOMMENDATION: This case should be referred to the Kentucky Board of Medical Licensure for further investigation.

cc: Kentucky Board of Medical Licensure

218A.202 Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.

(1) The Cabinet for Health Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy.

(2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the Cabinet for Health Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:

(a) A drug administered directly to a patient; or

(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:

(a) Patient identifier;

(b) Drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(5) The data shall be provided in the electronic format specified by the Cabinet for Health Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.

(6) The Cabinet for Health Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;

(f) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;

2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or

(g) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.

(7) The Department for Medicaid Services may use any data or reports from the system for the purpose of identifying Medicaid recipients whose usage of controlled substances may be appropriately managed by a single outpatient pharmacy or primary care physician.

(8) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction, except that:

(a) A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report if the peace officers specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in paragraph (a) of subsection (6) of this section, or with a law enforcement officer designated in paragraph (b) of subsection (6) of this section; and

(c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

(9) The Cabinet for Health Services, all peace officers specified in subsection (6)(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(10) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

(11) Knowing failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor.

(12) Knowing disclosure of transmitted data to a person not authorized by subsection (6) to subsection (8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony.

(13) The Governor's Office for Technology, in consultation with the Cabinet for Health Services, shall submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The pilot project shall:

(a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and

(b) Study the use of an interactive system that includes a relational data base with query capability.

(14) Provisions in this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (13) of this section.

(15) The Cabinet for Health Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.

(16) (a) The Cabinet for Health Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.

(b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

(c) The cabinet shall work with the Justice Cabinet for the development of a continuing education program for law enforcement officers about the purposes and users of the electronic system for monitoring established in this section.

Effective: July 13, 2004

History: Amended 2004 Ky. Acts ch. 68, sec. 1, effective July 13, 2004; and ch. 107, sec. 1, effective July 13, 2004. -- Amended 2002 Ky. Acts ch. 295, sec. 1, effective April 9, 2002. -- Created 1998 Ky. Acts ch. 301, sec. 13, effective July 15, 1998.

Legislative Research Commission Note (7/13/2004). This section was amended by 2004 Ky. Acts. chs. 68 and 107. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts. ch. 107, which was last enacted by the General Assembly, prevails under KRS 446.250.

Abuse, Diversion, and Regulatory Responses

Michael A. Moné, JD, FAPhA
Legal and Regulatory Affairs Consultant
April 7-8, 2005
Boston, Massachusetts

Abuse, Diversion, Regulatory Response

- Goals:
  - Decrease opportunities for diversion.
  - Decrease demand for substances to abuse.
  - Rational regulatory response.
- Methodology:
  - Education.
  - Research to facilitate understanding.
  - Understand change and the change cycle.

Abuse, Diversion, Regulatory Response

- Perhaps:
  - Appropriate prescribing.
  - Appropriate dispensing.
  - Appropriate regulatory response.
    - Boards
    - Criminal
    - Civil
    - Patients

Abuse, Diversion, Regulatory Response

- Chilling effect analysis
  - Corresponding liability
  - Understanding of standard of practice
    - Yours is not that of the profession.
    - Bell curve and where are you?
  - Civil and Criminal litigation
    - Usually not the best case selection. There ARE good cases out there to prosecute to serve as education to those who are educable.

Abuse, Diversion, Regulatory Response

- Retrospective Analysis
  - Medical and Pharmacy records
  - Not simply quantitative analysis
    - Quantitative analysis *may* form the limits of the inquiry
  - Number of doses is not dispositive.
  - Other conclusions to "addict."
    - e.g. inadequate pain control
    - Look toward quality of life.
    - What assessment has been done?

Abuse, Diversion, Regulatory Response

- Societal Response
  - Occasionally it is an over-response.
  - More than not it is a nimby.
  - Failure to differentiate between bad and evil
    - Modern society thinks in black and white
      - or blue and red.
    - Modern society is really shades of grey.
      - More difficult analysis
      - Tendency to be intellectually lazy.

Abuse, Diversion, Regulatory Response

- Key component: Balance
  - Regulatory response based upon jurisdiction.
  - May involve education of the profession and the public.
  - News and responses
  - Awareness of constituencies:
    - Legislature
    - Profession
    - Public
    - Patients

Abuse, Diversion, Regulatory Response

- Prescription Monitoring Programs
  - Better than what we had before…but
    - How is it to be used?
    - Who will analyze the data?
    - What will be the approach to outliers?
    - Is the information timely?
    - How is it to be accessed?
    - Who will have access?
    - Professional judgment?
    - Where is the program housed?

Abuse, Diversion, Regulatory Response

- Prescription Monitoring Programs
  - Comprehensive
  - Accurate
  - Time efficient
- What the include and what they don't or should not.
  - Prescription pad programs
  - Untoward effects based upon how they are "marketed."

Abuse, Diversion, Regulatory Response

- **Prescription Monitoring Programs**
  - How are laws interpreted?
  - Has money been put into treatment?
  - Is the system passive or active?
  - Are the successes of the program communicated to policy makers?
  - Are there plans for improvement?
  - Has there been close collaboration in the development of the program by the relevant constituencies?

Abuse, Diversion, Regulatory Response

- **How to use PMP**
  - Data mining for trend analysis
  - Suspected diversion
  - Suspected over-utilization
  - Unprofessional conduct
  - Excessive and inappropriate prescribing and dispensing.
  - Education

Abuse, Diversion, Regulatory Response

- **PMP issues**
  - Jurisdiction
  - All prescribers
  - All dispensers
  - Out-of-State dispensers
  - Compact with surrounding states
  - Internet
  - HIPAA

Abuse, Diversion, Regulatory Response

- HIPAA
  - Fundamentally NOT a bar to communication.
  - State confidentiality requirements may be more stringent.
  - Used as an excuse.
  - HIPAA does not preclude professional dialogue among healthcare practitioners about the care and treatment of the patient.

Abuse, Diversion, Regulatory Response

- (H.R. 3870) introduced by Rep. Charlie Norwood (R-GA) would make grants available to states to establish prescription drug monitoring programs. Information reported to the state would be contained in an electronic program database that would be available to physicians and pharmacists providing treatment or services to a patient who they suspect may be misusing or diverting prescription drugs.

Abuse, Diversion, Regulatory Response

- Diversion
  - Has its roots in misuse and abuse.
    - grandmothers cigarettes….
    - Theft
    - Fraud
    - Manufacturer
    - Common carrier
    - Wholesalers
    - Practitioner's office
    - Pharmacy
    - Health care facilities

Abuse, Diversion, Regulatory Response

- Diversion
  - prescription
  - phone
  - fax
  - Internet – e-mails
    - International scope, generally not for state action
    - Requires Federal response

Abuse, Diversion, Regulatory Response

- Rationality
  - Reasonable person standard
- Balance
- Consistency
  - Same message from all Boards
- Accountability
- Liability
  - The great fear.

Abuse, Diversion, Regulatory Response

- Board response
  - Communication to profession of expectations.
  - Policy statement?
  - Administrative regulation?
    - What was the basis
  - Has it been disseminated?
  - Last revision date?

Abuse, Diversion, Regulatory Response

- Board Retreat or Special Meeting
- Invite others to participate.
- Balanced approach
- Education
- Awareness of policy environment

Abuse, Diversion, Regulatory Response

- Thank you.

Michael A. Moné
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Section 6. Printers, Reproducers or Distributors of Security Prescription Blanks. (1) A printer, reproducer or distributor of security prescription blanks shall require a written purchase order or request for security prescription blanks. A written purchase order or request shall remain on file for two (2) years.

(2) A purchase order or request shall be signed by:

(a) A practitioner whose name shall be printed on the security prescription blanks; or

(b) The chief medical official of a health care facility or pharmacist-in-charge of a pharmacy, if the security prescription blanks are requested on behalf of a practitioner who stamps, types or manually prints his name, address, telephone number and DEA number on the security prescription blank.

(3) The provisions of this section shall not apply to distributions between printers, reproducers, or distributors.

Section 7. Waiver of Security Prescription Blanks. (1) A practitioner or a pharmacy may apply in writing to the cabinet for a waiver from the requirement for security prescription blanks. A request for a waiver shall include:

(a) A detailed statement of the security features provided by the system proposed by the applicant for the prevention of forgery or alteration of an original prescription; or

(b) The format of the alternative prescription blank.

(2) The system or prescription blank proposed by the applicant shall provide a level of security equivalent to a security prescription blank.

(3) The cabinet shall grant or deny the application in writing within sixty (60) days after the request is received.

(4) When a waiver has been granted, the cabinet may suspend or revoke the waiver if the alternative system or alternative prescription blank does not provide security equivalent to a security prescription blank.

(5) Upon notification of denial, suspension, or revocation of the waiver of the requirement for a security prescription blank, the practitioner or pharmacy may request a hearing. The administrative hearing shall be conducted in accordance with 902 KAR 1:400. (25 Ky.R. 721; Am. 1074; 1366; eff. 12-16-98.)

902 KAR 55:110. Monitoring system for prescription controlled substances.

RELATES TO: KRS 218A.202

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.202, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202 directs the Cabinet for Health Services to establish an electronic system for monitoring Schedule II, III, IV, and V controlled substances that are dispensed in the Commonwealth or dispensed to an address within the Commonwealth. The purpose of the system is to improve access to controlled substances for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. Also the system will enable regulatory or law enforcement agencies to address violations of KRS Chapter 218A. The purpose of this administrative regulation is to establish the criteria for reporting prescription data, for providing reports to authorized persons, and for a waiver for a dispenser who does not have an automated recordkeeping system.

Section 1. Definitions. (1) "Patient identifier" means a patient's:

(a) Full name;

(b) Address, including zip code;

(c) Date of birth; and

(d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.

(2) "Pharmacy Universal Claim Form" means a form that:

(a) Is in the format of the "Pharmacy Universal Claim Form" incorporated by reference in Section 6 of this administrative regulation; and

(b) Contains the information specified by Section 2(2) of this administrative regulation.

(3) "Report" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance.

Section 2. Data Reporting. (1) A dispenser shall report all controlled substances dispensed after December 31, 1998.

(2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:

(a) Patient identifier;

(b) National drug code of the drug dispensed;

(c) Metric quantity of drug dispensed;

(d) Date of dispensing;

(e) Estimated days supply dispensed;

(f) Drug Enforcement Administration registration number of the prescriber;

(g) Serial number assigned by the dispenser; and

(h) The Drug Enforcement Administration registration number of the dispenser.

(3)(a) The data shall be transmitted within sixteen (16) days of the date of dispensing unless the cabinet grants an extension.

(b) An extension may be granted if a dispenser suffers a mechanical or electronic failure, or cannot meet the deadline established by paragraph (a) of this subsection for other reasons beyond his control. A dispenser shall apply in writing for an extension. An application for an extension shall state the reason why an extension is required, and the period of time for which the extension is required.

(c) An extension shall be granted to all dispensers if the cabinet or its agent is unable to receive electronic reports.

(4) Except as provided in subsection (7) of this section, the data shall be transmitted by:

(a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;

(b) Double sided, high density micro floppy disk; or

(c) One-half (1/2) inch nine (9) track 1600 or 6250 BPI magnetic tape.

(5) The data shall be transmitted in the format established by the "ASAP Telecommunications Format for Controlled Substances".

(6) The cabinet shall provide a toll-free telephone number for transmitting electronic reports by modem.

(7)(a) A dispenser, who does not have an automated recordkeeping system capable of producing an electronic report in the format established by "ASAP Telecommunications Format for Controlled Substances", may request a waiver from electronic reporting. The request shall be made to the cabinet in writing.

(b) A dispenser shall be granted a waiver, if he agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form".

Section 3. Compliance. (1) A dispenser shall be deemed to be the person who is registered with the U.S. Drug Enforcement Administration.

(2) A dispenser may presume that the patient identification information provided by the patient or the patient's agent is correct.

Section 4. Request for Report. (1) A written request shall be filed with the cabinet prior to the release of a report.

(2) A request for a report shall be made on Request for KASPER Report, Form DCB-15 except for a subpoena issued by a grand jury.

Section 5. Alternative Patient Identification Number. (1) If a patient does not have a Social Security number, or refuses to provide a Social Security number, the patient's driver's license number shall be used.

(2) If a patient does not have a Social Security number or a driver's license number, the number 000-00-0000 shall be used.

(3) The number "999-99-9999" shall be used if a patient or a patient's agent refuses to provide a Social Security number or driver's license number.

(4) If a patient is a child who does not have a Social Security number, the Social Security number, driver's license number, or the number "000-00-0000", as applicable, of the parent or guardian shall be used.

(5) If a patient is an animal, the owner's Social Security number,

or driver's license number, or the number "000-00-0000", as applicable shall be used.

(5) If a patient's Social Security number is not available, the Social Security number, or driver's license number, or the number "000-00-0000", as applicable, of the person obtaining the controlled substance on behalf of the patient shall be used.

(6) If the patient or the patient's agent refuses to provide a Social Security number or driver's license, the number 999-99-9999 shall be used.

Section 6. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "ASAP Telecommunications Format for Controlled Substances", American Society for Automation in Pharmacy, May, 1995;

(b) "Pharmacy Universal Claim Form"; and

(c) "Request for KASPER Report, DCB-15, 9-98".

(2) This material may be inspected, copied, or obtained at the Department for Public Health, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (25 Ky.R. 966; Am. 1367; eff. 12-16-98.)

902 KAR 55:115. Drug possession by hospice or home health agency.

RELATES TO: KRS 217.005-217.215, 217.992

STATUTORY AUTHORITY: KRS 194A.050, 211.090, 217.125, 315.300

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.300 authorizes the Cabinet for Health Services to promulgate administrative regulations that implement the possession of certain drugs by a hospice or home health agency. The purpose of this administrative regulation is to establish criteria that a pharmacy, hospice or home health agency must meet in order to insure that drugs belonging to a pharmacy, that are stored in a hospice or home health agency, are safe and effective for administration to patients.

Section 1. Authorized Employees. A pharmacy may place a legend drug listed in KRS 315.300 with an authorized employee of a hospice or a home health agency if the pharmacy maintains a record of the license that authorizes the employee to administer legend drugs.

Section 2. Written Agreement. Each party to a written agreement between a pharmacy and a home health agency or a pharmacy and a hospice shall maintain a copy of the written agreement.

Section 3. Protocol. (1) A protocol required by KRS 315.300 may be included in the written agreement or may be a separate document.

(2) If the protocol is a separate document, a copy shall be maintained by the pharmacy and by the hospice or home health agency.

(3) The protocol shall be reviewed not less than annually and modified if necessary.

Section 4. Records. (1) The pharmacy record of a drug placed with authorized employees of a hospice or home health agency shall be retained for five (5) years.

(2) The record of a drug administered by authorized employees of a hospice or home health agency shall be retained by the pharmacy for five (5) years. (25 Ky.R. 723; Am. 1369; eff. 12-16-98.)

1. Amount of codeine

1957 OAG 40469. Medicinal tablets, each containing 1/16 grain of codeine, packed in a package containing sixteen tablets making the total amount of codeine in the sixteen tablets one grain, are exempt from the provisions of the Uniform Narcotic Drug Act. (Annotation from former KRS 218.080.)

218A.200 Record-keeping and inventory requirements; penalties

(1) Every practitioner who is authorized to administer or professionally use controlled substances, shall keep a record of substances received by him, and a record of all substances administered, dispensed, or professionally used by him otherwise than by prescription. Every such record shall be kept for a period of five (5) years.

(2) Manufacturers and wholesalers shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them. Every such record shall be kept for a period of two (2) years.

(3) Pharmacists shall keep records of all controlled substances received and disposed of by them. Every such record shall be kept for a period of five (5) years.

(4) The record of controlled substances received shall in every case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which the drugs were sold, administered, or dispensed, and the kind and quantity.

(5) The keeping of a record under the federal controlled substances laws, containing substantially the same information as is specified in subsection (4) of this section, shall constitute compliance with this section.

(6) A copy of the detailed list of controlled substances lost, destroyed, or stolen shall be forwarded to the Cabinet for Health Services as soon as practical.

(7) (a) Every manufacturer, distributor, wholesaler, repacker, practitioner, pharmacist, or other person authorized to possess controlled substances shall take an inventory of all controlled substances in his possession at least every two (2) years.

(b) A substance which is added to any schedule of controlled substances and which was not previously listed in any schedule shall be initially inventoried within thirty (30) days of the effective date of the statute or administrative regulation which adds the substance to the provisions of this chapter. Thereafter, the substance shall be included in the inventory required by paragraph (a) of this subsection.

(8) Any person who violates any provision of this section shall be guilty of a Class A misdemeanor for a first offense and a Class D felony for subsequent offenses.

HISTORY: 1998 c 301, § 25, c 426, § 485, eff. 7-15-98
1972 c 226, § 21, eff. 7-1-72.

Legislative Research Commission Note: (7-15-98): This section was amended by 1998 Ky. Acts chs. 301 and 426 which do not appear to be in conflict and have been codified together.

Note: 218A.200 contains provisions analogous to former 218.090, repealed by 1972 c 226, § 33, eff. 7-1-72.

Source Note (1972): Former KRS 217.755, 218.090.

Prohibition: 218A.140

PRACTICE AND STUDY AIDS

Abramson, West's Kentucky Practice, Vol. 10, Substantive Criminal Law 28.88, n 16

CROSS REFERENCES

Storage of controlled substances in an emergency medication kit in certain long-term care facilities, 902 KAR 55:070

Prescription for Schedule II controlled substance, facsimile transmission or partial filling, 902 KAR 55:095

LIBRARY REFERENCES

Statutory requirements for maintenance of records by dealers in narcotics, 25 Am Jur 2d, Drugs, Narcotics, and Poisons § 24, 25

218A.202 Electronic system for monitoring controlled substances; penalty for illegal use of system

(1) The Cabinet for Health Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy licensed by the Kentucky Board of Pharmacy.

(2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every dispenser within the Commonwealth or who is licensed by the Kentucky Board of Pharmacy shall report to the Cabinet for Health Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:

(a) A drug administered directly to a patient; or

(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:

(a) Patient identifier;

(b) Drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(5) The data shall be provided in the electronic format specified by the Cabinet for Health Services unless a waiver has been granted by the cabinet to an individual dispenser.

(6) The Cabinet for Health Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) A state, federal, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient; or

(f) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction.

(7) The Cabinet for Health Services, all law enforcement officers, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(8) The data and any report obtained therefrom shall not be a public record.

(9) Knowing failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor.

(10) Knowing disclosure of transmitted data to a person not authorized by subsection (6) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony.

HISTORY: 1998 c 301, § 13, eff. 7-15-98

PRACTICE AND STUDY AIDS

Abramson, West's Kentucky Practice, Vol. 10, Substantive Criminal Law 20.82, n 13

218A.204 Administrative regulations to establish security requirements for prescriptions; waiver

The Cabinet for Health Services shall promulgate administrative regulations in accordance with KRS Chapter 13A that establish security requirements for all prescriptions written by practitioners. The administrative regulations shall include a procedure to obtain a waiver for prescription blanks that provide substantially equivalent protection against forgery.

HISTORY: 1998 c 301, § 14, eff. 7-15-98

218A.210 Controlled substances may be possessed only in original container; penalties

(1) A person to whom or for whose use any controlled substance has been prescribed, sold, or dispensed, by a practitioner or other person authorized under this chapter, may lawfully possess it only in the container in which it was delivered to him by the person selling or dispensing the same.

(2) Violation of subsection (1) of this section is a Class B misdemeanor for the first offense and a Class A misdemeanor for subsequent offenses.

HISTORY: 1992 c 441, § 6, eff. 7-14-92
1972 c 226, § 22

Note: 218A.210 contains provisions analogous to former 218.110, repealed by 1972 c 226, § 33, eff. 7-1-72.

Source Note (1972): Former KRS 217.751, 218.110.

PRACTICE AND STUDY AIDS

Abramson, West's Kentucky Practice, Vol. 10, Substantive Criminal Law 20.88, n 19, 20.90, n 8, 20.90, n 9

LIBRARY REFERENCES

Sale of narcotics, generally. 25 Am Jur 2d, Drugs, Narcotics, and Poisons § 22

NOTES OF DECISIONS AND OPINIONS

1. Constitutional issues
2. Penalty

1. Constitutional issues

701 FSupp 1316 (WD Ky 1988), Jeffers v Heavrin, reversed 932 F(2d) 1160, rehearing denied, certiorari denied 112 SCt 937, 502 US 1059, 117 LEd(2d) 108. A police officer has probable cause to arrest a racetrack patron after finding a pill bottle containing an unattached label and pills which the defendant patron claims are his allergy medicine and which the police officer is told by a superior officer are valium.

2. Penalty

865 SW(2d) 302 (Ky 1993), Kentucky Bar Ass'n v White. Pleading guilty to possession of prescription drugs not in proper container and developing drug and alcoholic dependency warrants public reprimand and order that help be sought from Lawyers Helping Lawyers Committee of State Bar Association.

218A.220 Persons exempt from chapter

The provisions of this chapter shall not apply to common carriers or to warehousemen, while engaged in lawfully transporting or storing such substances, or to any employee of the same acting within the scope of his employment; or to public officers or their employees in the performance of their official duties requiring possession or control of controlled substances; or to temporary incidental possession by employees or agents of persons lawfully entitled to possession, or by persons whose possession is for the purpose of aiding public officers in performing their official duties.

HISTORY: 1972 c 226, § 23, eff. 7-1-72

Note: 218A.220 contains provisions analogous to former 218.120, repealed by 1972 c 226, § 33, eff. 7-1-72.

Source Note (1972): Former KRS 218.120.

NOTES OF DECISIONS AND OPINIONS

1. Agent
2. Aiding public officer

1. Agent

579 SW(2d) 111 (Ky 1979), Harris v Com. An "agent" must have knowledge that the person for whom he is acting is a police officer in order to claim exemption from prosecution for drug offenses.

UNIFORM CONTROLLED SUBSTANCES ACT (1994)

Drafted by the

NATIONAL CONFERENCE OF COMMISSIONERS
ON UNIFORM STATE LAWS

and by it

APPROVED AND RECOMMENDED FOR ENACTMENT
IN ALL THE STATES

at its

ANNUAL CONFERENCE
MEETING IN ITS ONE-HUNDRED-AND-THIRD YEAR
IN CHICAGO, ILLINOIS
JULY 29 - AUGUST 5, 1994

SECTION 309. DIVERSION PREVENTION AND CONTROL.

(a) In this section, "diversion" means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(b) The [appropriate person or agency] shall regularly prepare and make available to other state regulatory, licensing, and law enforcement agencies a report on the patterns and trends of distribution, diversion, and abuse of controlled substances.

(c) The [appropriate person or agency] shall enter into written agreements with local, state, and federal agencies to improve identification of sources of diversion and to improve enforcement of and compliance with this [Act] and other laws and regulations pertaining to unlawful conduct involving controlled substances. An agreement must specify the roles and responsibilities of each agency that has information or authority to identify, prevent, or control drug diversion and drug abuse. The [appropriate person or agency] shall convene periodic meetings to coordinate a state diversion prevention and control program. The [appropriate person or agency] shall arrange for cooperation and exchange of information among agencies and with other States and the federal government.

(d) The [appropriate person or agency] shall report [annually] to the governor and to the presiding officer [of each house] of the [legislative assembly] on the outcome of the program with respect to its effect on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances in this State.

RESEARCH

Pharmacists' Knowledge of and Attitudes Toward Opioid Pain Medications in Relation to Federal and State Policies

David E. Joranson and Aaron M. Gilson

Objective: To assess Wisconsin pharmacists' knowledge of and attitudes toward the use of opioid analgesics in the management of chronic cancer and noncancer pain, and to explore the potential for these beliefs to interfere with pharmacist dispensing, the last link of the distribution chain of controlled substances to patients. ***Design:*** Mail survey. ***Setting:*** Urban and rural pharmacies, long-term care facilities, hospitals, and outpatient clinics in Wisconsin in 1998. ***Patients or Other Participants:*** Representative sample of Wisconsin pharmacists. ***Interventions:*** None. ***Main Outcome Measures:*** Responses to self-administered questionnaires. ***Results:*** Although most respondents were knowledgeable about the issues addressed in this study, there were important exceptions. Not all pharmacists knew what constitutes legitimate dispensing practices for controlled substances under federal or state policy in emergencies or for patients with terminal illnesses, and many were unaware of the important distinctions among addiction, physical dependence, and tolerance. Many respondents did not view the chronic prescribing/dispensing of opioids for more than several months to patients with chronic pain of malignant or nonmalignant origin as a lawful and acceptable medical practice; this was especially true when the patient had a history of opioid abuse. ***Conclusion:*** Pharmacists play a pivotal role in ensuring patient access to medications. Viewed in the context of federal and state controlled substances policies, our findings suggest that the incorrect knowledge and inappropriate attitudes of some pharmacists could contribute to a failure to dispense valid prescriptions for opioid analgesics to patients in pain.

J Am Pharm Assoc. 2001;41:213–20.

The pharmacist is a critical link in the chain of drug distribution to the patient, dispensing drugs that are available by prescription only. To dispense opioid analgesics, pharmacists must comply with the requirements of federal and state drug, pharmacy, and controlled substances laws. Pharmacists are "personal health care advisers"[1] to their patients, but they are also "gatekeepers" who must determine whether dispensing a prescription order will serve a legitimate medical purpose and be in the usual course of professional practice.[2,3] Pharmacists who lack knowledge about pain management and controlled substances policies could be a weak link if they make decisions that break the chain of distribution of valid prescriptions for opioid analgesics. In this article we examine the potential for pharmacists to act as barriers to patients seeking legitimate access to opioids for pain management.

A few researchers have evaluated pharmacists' beliefs and practices relating to pain management and the regulation of opioids. Early surveys examining attitudes about specific dispensing practices used pharmacies as the sample groups. In 1986 Kanner and Portenoy[4] reported that 29% of pharmacies randomly sampled in New York City did not stock Schedule II opioid analgesics because of a fear of being robbed; only 3% stocked oral morphine. In 1989 Kanner and Cooper[5] found that 38% of a national sample of pharmacies stocked oral morphine. Those that did not stock the drug indicated that the reasons were a lack of prescription demand and fear of robbery. The results from these two studies generally mirror those from surveys of pharmacies in other states, such as New Mexico (1992)[6] and South Carolina (1993),[7] and from a 2000 survey of New York City pharmacies.[8]

Several surveys have evaluated stocking issues and factors that influence dispensing practices, as well as pharmacist knowledge and attitudes about opioid analgesics and the legality of chronic opioid prescribing.[1,9–12] A 1994 survey of North Carolina pharmacists conducted by Krick, Lindley, and Bennett[10] showed that availability of opioid analgesics varied as a function of practice site. Pharmacists in chain and independent pharmacies generally reported stocking significantly lower quantities of opioids than did those in hospital pharmacies. While respondents viewed "conservative" physician prescribing (51%) and nurse administration (44%) as

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substantial impediments to cancer pain management, 28% cited both the risk of addiction and concern about being investigated as important barriers.

A survey of pharmacists in Utah[1] revealed deficiencies in knowledge about cancer pain management that could adversely influence their perception of the legitimacy of a prescription order and therefore the dispensing of opioids for the treatment of pain. For example, 51% of the respondents believed that the risk of addiction to opioids is high.

One study conducted in New Hampshire remains unique in that it allowed comparisons of the responses of pharmacists, physicians, and nurses regarding knowledge and attitudes about cancer pain management.[11] Most (88%) of the respondents viewed the underuse of opioid analgesics as the primary reason for unrelieved pain. Pharmacists reported that they managed cancer pain more frequently than did physicians and nurses. However, pharmacists felt their training in cancer pain management was inadequate, and they were less comfortable with this role than were physicians and nurses. There was no statistically significant difference among members of the three professions regarding perception of addiction risk for cancer patients being treated with opioids. Although the vast majority of physicians (91%), nurses (85%), and pharmacists (86%) believed that addiction was not a clinically relevant phenomenon with cancer patients, some of these health care professionals did view addiction as a legitimate concern.

More recently, Greenwald and Narcessian[12] published the results of a first-of-its-kind survey assessing pharmacists' attitudes toward the legality of prescribing opioids in differing clinical situations. Of a small sample of 36 pharmacists practicing in New Jersey, only 75% considered prolonged prescribing for cancer pain to be a lawful and acceptable medical practice. When the patient had a history of opioid abuse, only 36% of respondents viewed the prescribing as lawful and acceptable. Pharmacists' confidence in the legal and medical acceptability of prescribing decreased further when the patient had chronic nonmalignant pain (17%) and chronic nonmalignant pain with a history of opioid abuse (3%). A majority of responding pharmacists (56% for the nonmalignant pain scenario and 83% when the patient had nonmalignant pain and a history of opioid abuse) believed that prescribing for the latter two scenarios should be discouraged or investigated, even though neither of these practices is illegal or necessarily inappropriate.

Objectives

The objectives of this survey were (1) to assess the knowledge and attitudes of Wisconsin pharmacists about the use of opioids in the management of chronic cancer and noncancer pain and (2) to explore the potential for these beliefs to interfere with pharmacist dispensing, which is the last link in the chain of distribution of controlled substances to patients.

Methods

A 51-item questionnaire was developed by the Pain & Policy Studies Group (PPSG) at the University of Wisconsin, Madison, using several questions from previous surveys.[13] The instrument contained questions about demographics; views on dispensing Schedule II opioids; the nature and extent of addiction, abuse, and diversion; judging the validity of prescriptions; perceived effects of legal requirements; knowledge of controlled substances dispensing requirements; and the legality of certain prescribing scenarios. Although the survey instrument was not psychometrically evaluated for validity and reliability, it was pilot-tested for content and design with 10 pharmacists (8 practitioners and 2 professors from the University of Wisconsin) in the city of Madison.

The survey was mailed in April 1998 to a random sample of 1,000 licensed pharmacists obtained from a list provided by the Wisconsin Department of Licensing and Regulation. No attempt was made to oversample for specific respondent characteristics, such as size of the community in which the pharmacist practices or principal practice setting. A cover letter stated the subject of the survey but did not mention the specific issues to be examined. The letter also assured respondents of confidentiality. Reminder postcards were mailed twice to nonrespondents. Responses were tabulated, and frequencies and descriptive statistics were calculated for each item.

Results

Sample

The overall sample size was reduced to 899 after 101 surveys were returned as undeliverable or because the pharmacist was no longer practicing. A total of 557 questionnaires (62%) were returned, of which 547 (98%) were usable, for an overall response rate of 61%.

Table 1 shows respondents' demographic characteristics. The characteristics of this sample, such as age, sex, and education, are similar to those of the general population of pharmacists in the state. Table 2 shows respondents' ratings of the adequacy of their undergraduate professional education about controlled substances requirements and the use of opioids for pain management.

Views on Addiction, Abuse, and Diversion

Respondents were asked the meaning of "addiction" and given several characteristics from which to select: physical dependence, psychological dependence, tolerance, other, and don't know. Respondents could choose more than one answer. More than three-quarters (79%) viewed addiction as some combination of physical dependence, psychological dependence, and tolerance; 88% of respondents said that addiction means physical dependence; 84% indicated psychological dependence; and 36% chose tolerance. Of this sample, 12% considered physical

dependence alone to be sufficient to indicate addiction, and 10% chose psychological dependence only. Less than 1% reported that they did not know what characterized addiction.

One item asked respondents to estimate the approximate incidence of psychological dependence (defined in the questionnaire as "compulsive use for psychic effects") that results from the treatment of pain using opioids. Only 9% viewed psychological dependence as an extremely rare event and chose less than 1 in 1,000; 13% thought the incidence was 1 in 1,000; 25% chose 1 in 100; 16% chose 1 in 10; and nearly 40% did not know.

Almost one-half of the respondents (46%) viewed diversion and abuse of prescription opioid analgesics as a problem in their community, whereas 33% did not. Of the former, 10% (4% of the total sample) said it was a serious problem, 55% (24% of the total sample) a moderate problem, and 35% (15% of the total sample) a minor problem.

Most pharmacists (87%) were confident they could recognize when a person was attempting to obtain a controlled substance from a pharmacy for other than legitimate medical purposes. This situation was considered rare by 39%, and 55% indicated that it happened occasionally. Two-thirds (68%) were aware of situations where pharmacists suspected that patients with inadequately treated pain were "drug seekers" because they had requested additional pain medications.

Views on Stocking Schedule II Opioids

One-half of the respondents (51%) indicated that during the last 2 years they rarely had been unable to dispense a Schedule II opioid analgesic because the medication was not in stock; 35% stated that this happened occasionally and only 1% reported it happened often. This situation had never been encountered by 14% of the respondents. Choosing from a list the factors they believed limit the stocking of Schedule II opioid analgesics at their primary practice site, respondents indicated lack of prescription orders (78%), medication cost (38%), fear of theft or robbery (12%), inadequate reimbursement (8%), fear of pilfering (5%), concern about investigation by a regulatory agency (5%), and potential for drug addiction (2%). In addition, 48% reported that they would not be willing to provide a Schedule II opioid to another pharmacy that temporarily ran out of stock.

Views on Dispensing Schedule II Opioids

Eighty-two percent of pharmacists indicated that they would be willing to dispense a limited quantity of Schedule II opioid medication for a bona fide patient emergency without a written prescription order if they received the prescription order from a practitioner by telephone. However, 18% would not dispense in this situation. Respondents reported that they would never (4%), occasionally (33%), often (23%), and always (40%) decline to dispense a Schedule II opioid if the original prescription order lacked complete information. When considering the appropriate dosage of an opioid analgesic, 38% of pharmacists somewhat agreed and 9% strongly agreed that a dosage greater than that recommended in the *Physicians' Desk Reference (PDR)* or product package insert is probably excessive and cause for concern about the appropriateness of a prescription order.

Table 1. Demographic Characteristics of Respondents (n = 547)

Characteristic	Descriptive Results[a]
Age in years (mean ± standard deviation)	45 ± 12
Age in years (range)	24–76
Sex (%)	
Men	64
Women	36
Year of degree (median)	1978
Year of degree (range)	1943–1997
Highest degree attained (%)	
Bachelor of science	92
Graduate	8
Practice setting (%)	
Community chain pharmacy	30
Community independent pharmacy	24
Hospital	22
Other	25
Location of practice (%)	
Rural	18
Suburban	19
Urban	64
Population of community of practice (%)	
< 25,000	29
25,000–100,000	29
100,001–500,000	19
500,001–1,000,000	16
> 1,000,000	8
Involved in hospice (%)	
Not at all	35
Rarely	27
Occasionally	24
Often	14
Aware of Wisconsin Cancer Pain Initiative (%)	
Yes	33
No	67

[a]Columns may not total 100% due to rounding.

Table 2. Perceived Adequacy of Education

Self-Rating	About Controlled Substances Requirements[a] No. (%)	About Opioids and Pain Management No. (%)
Poor	24 (5)	64 (12)
Fair	151 (28)	197 (38)
Good	266 (49)	229 (44)
Excellent	97 (18)	34 (7)

[a]Columns may not total 100% due to rounding.

Experience with Controlled Substances Investigations

Regulatory agencies had investigated or audited 14% of respondents in regard to controlled substances. When all respondents were asked to estimate the likelihood that they would be audited or investigated by a drug regulatory agency sometime during their career, the mean response ± standard deviation was 35% ± 28% (range, 0% to 100%). Seventeen percent agreed that their records for controlled substances would not pass scrutiny by a regulatory agency.

Knowledge of Controlled Substances Requirements

Pharmacists were asked whether they believed their knowledge of relevant controlled substance regulations to be adequate: 53% somewhat agreed, 29% strongly agreed, 16% somewhat disagreed, and 2% strongly disagreed. Sixty-four percent of respondents knew that federal regulations allow pharmacists to partially dispense a Schedule II opioid analgesic for a terminally ill patient living at home. An equal percentage was aware that this is allowed by state regulations, while 4% somewhat disagreed, 15% strongly disagreed, and 16% did not know. In addition, just over one-third of respondents (35%) believed that the requirements for prescribing, dispensing, and managing controlled substances had a negative effect on their appropriate medical use.

Perceived Legality and Medical Acceptability of Prescribing and Dispensing Opioids for Chronic Pain

Pharmacists were asked to give their opinion about the legality and medical acceptability of prescribing and dispensing opioids for more than several months in four patient scenarios involving chronic malignant and nonmalignant pain with and without a history of opioid abuse. There were three possible levels of legality for each scenario: (1) lawful and generally acceptable medical practice, (2) lawful but generally not accepted medical practice that should be discouraged, and (3) a probable violation of federal or state controlled substances or medical practice laws that should be investigated. Respondents also were given a "don't know" option. Only one response could be chosen for each scenario. Table 3 contains the frequencies of responses for each chronic pain scenario.

Cancer Pain Scenarios

The vast majority (93%) of respondents were confident in the legality and medical acceptability of prescribing and dispensing opioids for more than several months for pain patients with a malignancy. If the cancer patient with chronic pain had a history of opioid abuse, the proportion of respondents expressing confidence decreased to less than two-thirds (64%). The practice would be discouraged by 17%, and 6% would consider it to be a probable violation of law. Respondents chose "don't know" most often (12%) for this scenario.

Nonmalignant Pain Scenarios

If chronic pain is of nonmalignant origin, 57% of respondents were confident that prescribing and dispensing opioids for an extended period is legal and accepted medical practice. Thirty percent perceived the practice to be legal, but would discourage it. Six percent believed that the practice probably was illegal and should be investigated.

Only 8% of the pharmacists viewed the prescribing and dispensing of opioids for more than several months to a patient with chronic nonmalignant pain and a history of opioid abuse as legal and acceptable medical practice. Almost half (47%) thought the practice was legal but would discourage it; 35% believed the practice to be in probable violation of controlled substances or medical practice laws that should be investigated.

Other Issues

Respondents were asked whether they believed marijuana was effective for treating pain. The responses were: strongly agree (4%), somewhat agree (15%), somewhat disagree (18%), strongly disagree (22%), and don't know (42%).

Table 3. Perceptions of Legality and Medical Acceptability of Extended Prescribing/Dispensing of Opioids

Response	Chronic Cancer Pain[a] No. (%)	Chronic Cancer Pain with History of Opioid Abuse No. (%)	Chronic Noncancer Pain No. (%)	Chronic Noncancer Pain with History of Opioid Abuse No. (%)
Lawful and generally acceptable medical practice	488 (93)	336 (61)	299 (57)	43 (8)
Lawful but generally not acceptable medical practice that should be discouraged	7 (1)	92 (17)	159 (30)	249 (47)
Violation of federal or state controlled substances or medical practice laws or regulations that should be investigated	13 (2)	34 (6)	33 (6)	184 (35)
Don't know	17 (7)	65 (12)	34 (7)	50 (10)

[a]Columns may not total 100% due to rounding.

Discussion

The results of this study should be viewed in the context of federal and state laws, which establish that the only lawful way for a patient to obtain a prescription drug is through a pharmacist. Controlled substances policies further establish that pharmacists have a legal duty to not dispense a controlled substance in a manner inconsistent with regulatory requirements, including for other than legitimate medical purposes and other than according to the regulations for emergency and partial dispensing. However, if a pharmacist fails to dispense a valid prescription because of incorrect knowledge or inappropriate attitudes, the last link in the legitimate medication distribution chain is broken.

Responses to our survey suggest that, while most pharmacists would dispense appropriately, a significant minority might not dispense a valid prescription because they have incorrect knowledge or misconceptions about what is legitimate practice under federal or state policy. For example, some pharmacists would decline to dispense an opioid analgesic during a bona fide patient emergency if the prescription order was received from a practitioner by telephone, even though such dispensing is lawful under federal and state policies.[14]

Many respondents would consider a dosage of an opioid that is greater than that recommended in the *PDR* or product package insert to be excessive and cause for concern about its appropriateness. However, once a drug has been approved for use under the Federal Food, Drug, and Cosmetic (FD&C) Act, a physician can prescribe it in doses and for uses not mentioned in the approved labeling.[15] Indeed, a physician's ability to prescribe a drug according to his or her best knowledge and medical judgment is stated in the *PDR*:

> The [Food and Drug Administration] has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug ... The [FDA] also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling.[16]

Some respondents also did not know that federal[17] or state regulations, including those of Wisconsin,[18] authorize partial dispensing of Schedule II opioids for a terminally ill patient living at home.

Compared with the New Jersey pharmacists participating in Greenwald and Narcessian's study,[12] Wisconsin pharmacists reported a higher level of confidence in the legality and medical acceptability of prescribing or dispensing opioids for more than several months for all four patient scenarios mentioned in the survey. Nevertheless, a significant minority of Wisconsin pharmacists felt that opioid use in these scenarios should be discouraged or investigated, even when prescribing opioids could be within the legitimate practice of medicine and, therefore, lawful under federal and state policies so long as the purpose remains the treatment of pain.[19–21] A pharmacist's belief that certain patient characteristics affect the legality of prescribing and dispensing of some pain management medications has the clear potential to result in decisions to not dispense valid prescriptions.

Diversion of Controlled Substances

Diversion from pharmacies by criminal acts, including robbery, is a significant source of prescription drugs on the illicit market.[22] Many pharmacists in this sample reported that diversion of prescription opioid analgesics was a moderate or serious problem in their community, that they knew of attempts by individuals to obtain controlled substances from a pharmacy for illicit purposes, and that there had been a theft or robbery in their pharmacy during the last 5 years.

These results suggest that pharmacy theft may be a significant source of diversion in the state, and that state and federal agencies should review diversion from pharmacies to determine its actual extent. This can be accomplished easily by reviewing information from the Drug Enforcement Administration (DEA) Form 106, which, by law, pharmacists must complete and submit in the event of losses of controlled substances. The results of such a review could inform the development of a strategy to apprehend perpetrators of pharmacy crime and assist pharmacists in preventing this type of diversion.

Pseudoaddiction

Respondents were aware that patients were not being adequately treated for their pain, and knew of frequent occasions when other pharmacists misinterpreted patient requests for additional medications for inadequately treated pain as drug-seeking behavior related to addiction. Such misinterpretations can occur when health care personnel inappropriately perceive pain-relief-seeking behavior as maladaptive drug-seeking behavior. This is an iatrogenic phenomenon termed "pseudoaddiction."[23]

At the same time, respondents were confident in their ability to identify attempts to obtain controlled substances for other than legitimate medical purposes. Suspicion that a patient is obtaining prescription orders for abuse could lead to a correct decision to not dispense, according to the legal responsibility of pharmacists to not dispense for other than legitimate medical purposes.[24] It is encouraging that many of these pharmacists do not assume that a patient's efforts to obtain more pain medications are invariably a sign of drug dependence and/or addiction.

Definitions of and Risk for Addiction

Most definitions of addiction selected by respondents included both physical and psychological dependence, and, to a lesser extent, tolerance. Some pharmacists defined addiction solely on the basis of the manifestation of withdrawal symptoms (i.e., physical dependence), which by itself is insufficient to define addiction/drug dependence (i.e., characterized by a maladaptive behavioral syndrome)[25,26] (see Table 4). Physical dependence is common when opioids are used to manage chronic pain. Consequently, confusing physical dependence with addiction or drug dependence can lead to an exaggeration of the degree of risk of addiction among chronic pain patients who are being treated with

Table 4. Definitions of Addiction, Physical Dependence, and Tolerance

Addiction—A neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Also referred to as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy for pain and should not be considered addiction.

Physical dependence—A physiologic state of neuro-adaptation characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. By itself, physical dependence does not equate with addiction.

Tolerance—A physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

Adapted from Reference 27.

opioids. Since it is unlawful to dispense opioids for maintenance of narcotic addiction (unless separately registered), confusing physical dependence and addiction could lead a pharmacist to make an incorrect decision to not dispense.

When asked to approximate the incidence of psychological dependence resulting from the treatment of pain with opioids, two out of three pharmacists who chose a response other than "don't know" believed that psychological dependence was a relatively common occurrence among all pain patients receiving opioids. Overestimation of the incidence of iatrogenic psychological dependence is common among health care providers, as demonstrated in previous studies.[1,11,13,28,29] For example, 54% of a sample of Arkansas pharmacists believed that the risk of addiction to opioids is high.[29] A comparable percentage of members of state medical boards, the agencies that license and discipline physicians, considered the potential for addiction to be high when opioids are used to treat pain.[13,28] Furthermore, almost half of these respondents did not know the likelihood of psychological dependence as a result of opioid treatment for pain. These findings indicate a lack of knowledge about the relatively low incidence of addiction (or psychological dependence). Greater effort is needed to provide pharmacists (and other health care providers) with an up-to-date understanding of the characteristics and risk of addiction when opioids are used to treat pain.

Stocking and Dispensing Issues and Concerns About Investigation

To dispense a prescribed opioid, a pharmacist must have it on hand. In previous surveys, concerns about theft or regulatory investigation were a primary cause for reluctance to stock and dispense Schedule II controlled substances, but this sample of Wisconsin pharmacists did not identify such concerns as a primary reason for not stocking opioids. When a Schedule II opioid analgesic was not stocked, it was due primarily to a lack of prescription orders or medication cost. However, pharmacies can arrange to obtain a needed medication from another pharmacy. Many of these pharmacists were reluctant to provide Schedule II opioids to another pharmacy that did not have the drug in stock.

Few pharmacists in our study had been investigated or audited by a state regulatory agency; however, these respondents were uncertain that their pharmacy records would stand up to scrutiny if audited. Studies in other states have shown that concerns about regulatory investigation are associated with decisions not to stock Schedule II controlled substances.[4–6,8] Our findings to the contrary may be due to the replacement of routine pharmacy inspections in Wisconsin with a self-inspection program and targeted investigations as needed.

Other Clinical Issues

About one in five of the pharmacists in our sample indicated some agreement about the effectiveness of marijuana for treating pain. However, the medical use of marijuana remains a research question, not a clinical one, since marijuana is not an approved drug for pain management. Hence the response may have been influenced more by media stories about medical marijuana than by pharmacists' professional education.

It is interesting to note that although most respondents were not currently involved in hospice care, nearly one-third were aware of the Wisconsin Cancer Pain Initiative. This finding likely reflects the involvement of pharmacists and the state pharmacy association in the initiative as well as publicity about the initiative in the state pharmacy journal.[30]

Finally, a majority of pharmacists rated their education about controlled substances requirements as either good or excellent, whereas only about half gave the same rating to their education about pain management. This result is similar to that of Furstenberg et al.,[11] who found that pharmacists were significantly less likely than physicians or nurses to consider their training in cancer pain management to be adequate or better-than-adequate.

Recommendations

Our results suggest that Wisconsin pharmacists need additional education about the use of controlled substances for pain management. With new discoveries about pain physiology and opioid pharmacology, as well as revised definitions of addiction,[31,32] these topics are being incorporated into medical and nursing education.[33] It would be desirable to review whether pharmacy texts and curricula have been updated to reflect current knowledge, and a study is currently being conducted as part of the Last Acts campaign to address this issue.[34] Our findings indicate that, in addition to basic professional education, pharmacists need continuing education programs focusing on pain, opioid analgesics, the characteristics and risks of addiction, and federal and state controlled substances and pharmacy policies, including recent changes relat-

ing to partial dispensing. Pharmacists, like physicians, should know enough about pain management and addiction to distinguish between acceptable and unacceptable practices by today's standards. The PPSG has prepared an annotated bibliography of journal articles addressing issues related to pain management and end-of-life care, which can be ordered through the publications list on the Last Acts Web site (www.lastacts.org).

It may help to develop criteria that would assist pharmacists as they evaluate and respond to various dispensing situations that pose risks for incorrect decisions. Such an approach would emphasize the pharmacist's professional responsibility to not dispense invalid prescriptions and to dispense those that are valid. We concur with the standard of decision making suggested by Brushwood and Carlson to achieve a balance between these two obligations:

> …regulatory policy should not insist that the uncertainty of a suspicious prescription always be resolved in the most conservative way, by a pharmacist refusing to fill the prescription.[24]

In this respect, it is important to note that DEA has stated that controlled substances "have a legitimate clinical use and a practitioner should not hesitate to prescribe, dispense or administer them when they are medically indicated."[22]

To further the objective of improving pain management while preventing diversion, we recommend that state pharmacy boards consider adopting guidelines or policy statements that

- Encourage pharmacists to become more involved in pain management
- Encourage continuing education about pain, opioid analgesics, addiction, and controlled substances policy
- Explain their criteria for judging the validity of various dispensing practices that may be at issue
- Correctly define pain and addiction-related terms, such as tolerance, physical dependence, addiction, and pseudoaddiction.

State medical boards are at the forefront of issuing new policies to encourage effective pain management,[35–37] with medical boards in 35 states having adopted such policies (see the PPSG Web site at www.medsch.wisc.edu/painpolicy/matrix.htm). To date, only the pharmacy boards of California and Washington have developed such guidance. We encourage pharmacy boards to undertake this effort in cooperation with the boards of medicine and nursing in their state. The results of such a cooperative approach were on view recently in North Carolina, where the boards of medicine, pharmacy, and nursing developed a joint policy statement on pain management and end-of-life care.[38] However, new guidelines alone will have little effect unless they are disseminated to pharmacists and publicized.

Finally, we urge pharmacy associations to sponsor educational programs about pain management. State pharmacy boards can play an important role in these educational programs by having representatives present to clarify board policies for dispensing controlled substances and to answer questions. Implementation of these recommendations could benefit the public health by reducing diversion of prescription opioid analgesics and its consequences and costs, and by strengthening the pharmacist's role as the last critical link in the chain of distribution of pain medications to patients.

Limitations

There are two important limitations to this study. First, results from a survey of Wisconsin pharmacists may not generalize to pharmacists in other states. Second, the validity of the results may be affected by the usual limitations of self-report questionnaires and thus may not fully reflect the respondents' beliefs, attitudes, or actual practices.

Conclusion

Our findings show a need to further improve Wisconsin pharmacists' understanding of pain management and requirements for prescribing, dispensing, and managing controlled substances. Although most respondents were knowledgeable about the issues addressed in this study, there were important exceptions. A number of pharmacists did not know what constitutes legitimate dispensing practices in certain situations according to federal and state policies. Some pharmacists had been unable to dispense Schedule II opioids because they were not in stock; others would not be willing to provide opioids to another pharmacy that was out of stock. Some would decline to dispense a telephone order for a Schedule II opioid needed in an emergency. Many pharmacists believed that doses greater than those recommended in the *PDR* are probably excessive and a cause for concern. Many did not appreciate the important distinction between addiction and physical dependence or tolerance. Many respondents did not view the dispensing of opioids for more than several months for chronic pain as a lawful and acceptable medical practice. If any of these responses were translated into practice, patients with valid prescriptions might not be able to obtain their pain medications.

It is our hope that our results and recommendations for improving pharmacist education and addressing pharmacy diversion will be discussed and critiqued, and that these discussions will lead to additional research as well as action on the part of pharmacy associations and pharmacy boards. The pharmacist can and should play an important role on the health care team by identifying cases of inadequate pain relief and communicating with the patient and caregivers about the need to improve pain management.

This study was supported by grant 031461 from the Robert Wood Johnson Foundation, received September 6, 2000.

The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, and honoraria.

The authors gratefully acknowledge the assistance of pharmacists Joseph B. Wiederholt, PhD, and Theodore M. Collins for review of the survey; Martha M. Maurer, BS, for survey dissemination and data entry; and John M. Nelson, MS, for database development.

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Federation of State Medical Boards

Promoting Balance and Consistency in the Regulatory Oversight of Pain Care

Table of Contents

Creating a Regulatory Environment Encouraging Appropriate Pain Care

Presented by:

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Creating a Balanced Regulatory Environment for Pain Management

Federation of State Medical Boards of the US
Boston, Massachusetts
April 2005

Pain & Policy Studies Group
University of Wisconsin Medical School
World Health Organization Collaborating Center
www.medsch.wisc.edu/painpolicy

Research, Education and Policy Evaluation

- ✓Surveys of board members (1991, 1997, 2004)
- ✓Educational workshops (1994-present)
- ✓Model policy development
- ✓Monitoring state policy trends
- ✓Evaluation of state policies
- ✓How states are improving policies

2004 Survey of medical board members about knowledge, attitudes and policy (Preliminary results)

When opioids are used for an extended period to treat pain

- Physical dependence is common: 78%
- Withdrawal symptoms are common: 76%
- Tolerance is common: 83%
- Addiction is common: 46%

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Diversion and abuse of prescription opioids is a problem in my state

Yes: 86%*

- Minor: 15%
- Moderate: 52%
- Severe: 31%*

* Significantly higher than on previous surveys

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Prescribing an opioid analgesic for more than several months to treat a patient with:

	Lawful/generally acceptable medical practice (1991, 1997, 2004)
Chronic cancer pain:	75%, 82%, 87%*
Chronic cancer pain/Hx abuse:	46%, 57%, 65%*
Chronic non-cancer pain:	12%, 33%, 67%*
Chronic non-cancer pain/Hx abuse:	1%, 6%, 21%*

* Significantly higher than on previous surveys

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Importance of medical board to have a pain management/prescribing policy

Somewhat important:	**22%**
Very important:	**71%**
• **Useful in improving pain management:**	**78%**

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Monitoring State Pain Policy

- **State legislatures**
- **State licensing boards (Med, Rx, RN)**
  - **Regulations**
  - **Guidelines**
  - **Policy statements**

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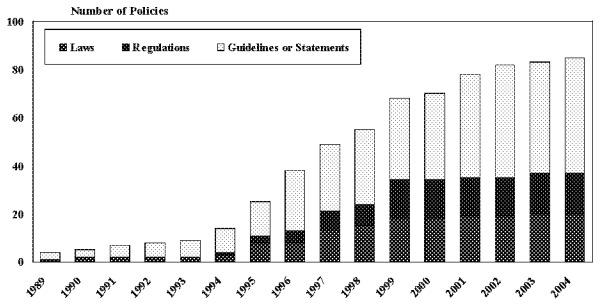
State Pain-Specific Policies

1989 - 2004



By: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2005
Updated January, 2005

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Why is state policy important?

- Authorizes medicine, pharmacy, use of drugs
- Defines scope of professional practice
- Prohibits unprofessional conduct
- Regulates prescription of controlled drugs
- Criminalizes unauthorized distribution

When is government regulation more restrictive than necessary?

- Conflicts with medicine and science
- Confuses lawful and unlawful conduct
- Dictates professional decisions
- Presents undue burdens
- Blocks access to care

How do you tell?

Evaluate policy

PPSG Policy Evaluation Method

- Based on valid public health and legal principles
- Central principle is "Balance"

Policy Framework for "Balance"

- States-regulate professional practice
- FFDCA-regulates drug efficacy and safety
- CSA-recognizes CS necessary for public health
- CSA-control system for app'd drugs, penalties
- CSA-HHS binding on control decisions

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The Principle of "Balance"

- Opioids safe and effective, necessary
- Opioids have potential for abuse, need control system
- "Controlled substance" does not change medical value
- Policy governing drugs and professional practice should not conflict with medicine
- Efforts to address diversion must not interfere with medical practice and patient care

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Recognition: Principle of "Balance"

- Institute of Medicine
- American Cancer Society
- National Cancer Institute
- Federation of State Medical Boards
- National Assn of Attorneys General
- Drug Enforcement Administration
- American Medical Association
- State pain initiatives

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Using "Balance" to Evaluate State Policies

- Central principle (Balance)
- Derive evaluation criteria (17)
- Peer review of evaluation methodology
- Collect policies
  - Laws, regulations, guidelines (400 in 2003)
  - Pain, controlled substances, medical and pharmacy practice
- Evaluate policies (3 researchers)
- Analyze, report results (EG1, EG2, PRC)

Examples of state policies

- Not for patients with addiction or Hx
- Consultation mandatory for every pt
- Only after failure of all other Tx
- "Drug holidays"
- Special government Rx form
- Rx quantity limited
- Rx validity expires in a few days
- Pharmacist reports all C IIs to Attny Gen

The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of a terminal illness.

Alabama Medical Board Guideline
Encourages pain management
Criterion 4 (+)

28 states (55%) have policies that encourage pain management

Physicians should not fear disciplinary action from the Board for prescribing controlled substances, including opioid analgesics, if for a legitimate medical purpose, including for pain…

Addresses fears of regulatory scrutiny
Criterion 5 (+)

34 States (67%) have policies that address fears of regulatory scrutiny

…tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

Kansas Medical Board Guidelines
Does not confuse physical dependence with addiction
Criterion 7 (+)

26 states (51%) have policies which clarify that physical dependence and tolerance are <u>not</u> the same as addiction

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Drug dependent person means a person who is using a drug, controlled substance or alcohol, and who is in a state of psychic or physical dependence, or both…this definition shall include those persons commonly known as "drug addicts."

Pennsylvania Uniform Controlled Substances Act

Physical dependence confused with addiction

Criterion 12 (-)

18 states (35%) have policies that confuse physical dependence/tolerance with addiction

Prescriptions for controlled substances in schedules II and III…cannot be written for more than 100 dosage units, nor can more than 100 dosage units be dispensed at one time.

- Delaware

Medical decisions restricted

Criteria 13c (-)

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[Drug holidays] allow you to check to see whether the original symptoms recur when the drug is not given - indicating a continuing legitimate need for the drug or whether withdrawal symptoms occur – indicating drug dependence.

- Georgia

Not good medical practice; confuses physical dependence and addiction

Criteria 16 (-)

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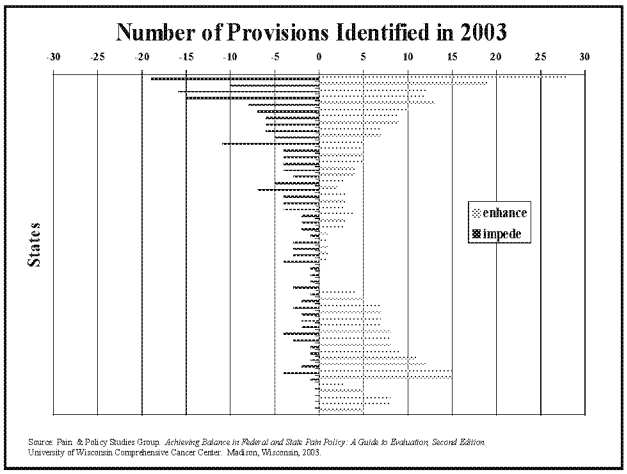
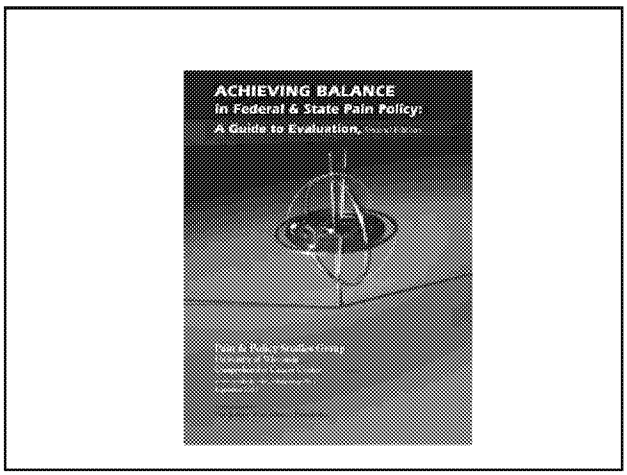
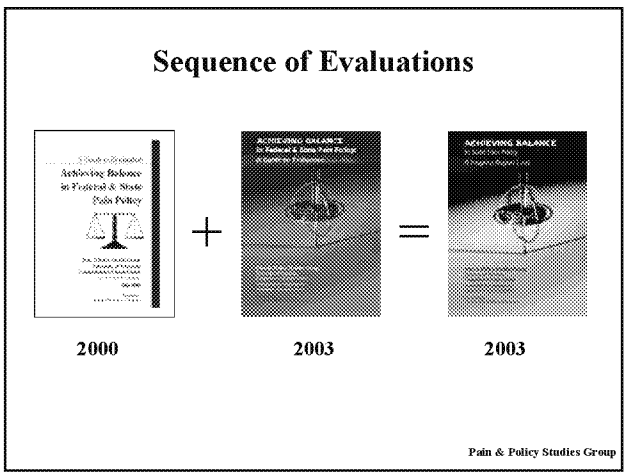

Number of Provisions Identified in 2003
-30 -25 -20 -15 -10 -5 0 5 10 15 20 25 30
States
enhance
impede
Source: Pain & Policy Studies Group. Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation, Second Edition. University of Wisconsin Comprehensive Cancer Center. Madison, Wisconsin, 2003.


ACHIEVING BALANCE
in Federal & State Pain Policy:
A Guide to Evaluation,


Sequence of Evaluations
2000
2003
2003
Pain & Policy Studies Group

State Grade Distribution - 2003

A	B+	B	C+	C		D+	D	F
	AL	FL	AR	AK	NY	AZ	NH	
	KS	IA	MD	CA	ND	CT	NJ	
	MA	ME	MI	CO	OH	DE	RI	
	NE	NC	NV	ID	OK	DC		
	NM	PA	OR	KY	TN	GA		
		SD	SC	MN	TX	HI		
		WA	UT	MS	VT	IL		
		WV	WI	MO	VA	IN		
				MT	WY	LA		

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16 States Improved

(2000 to 2003)

Florida	Missouri
Hawaii	Nevada
Idaho	New Mexico
Iowa	Ohio
Kansas	South Carolina
Kentucky	Tennessee
Massachusetts	West Virginia
Michigan	Wisconsin

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What Contributed to Positive Change?

- Addition of positive provisions
  - Board policies based on the Model Guidelines
  - Joint board policy statements
  - Board palliative care and end-of-life care guidelines
- Repeal of negative provisions
  - PMP with special government form
  - Short validity periods (2 weeks or less)
  - Mandated consultation

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Sources of Policy Change

- State medical, pharmacy, nursing boards
- State legislatures

Catalysts for Change

- Federation of State Medical Boards
- State Pain Initiatives
- Community-State Partnerships
- End-of-Life Care Coalitions
- American Cancer Society
- National Association of Attorneys General
- Leadership of key individuals

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Joint Policies
Pain Management and End of Life Care

Medicine, Nursing and Pharmacy

Kansas	North Carolina
Montana	Washington
Minnesota	West Virginia

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Dissemination of Guidelines by State Medical Boards:

Examples of Excellence

- Minnesota Board of Medical Examiners
  - Endorsed Model Guidelines
  - Sponsored 10 educational seminars in 2001
- North Carolina Medical Board
  - Several policies on chronic pain, end of life care
  - Sustained education and communications

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Improving State Pain Policies

- Identify, remove negative provisions
- Add positive provisions
- Disseminate, educate
- Cooperate: healthcare, enforcement, regulatory

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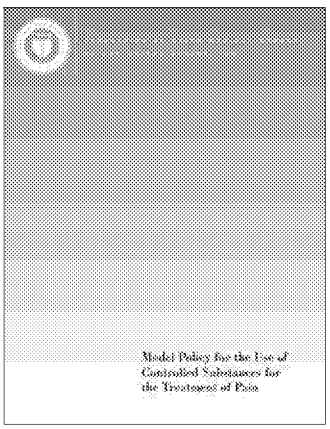

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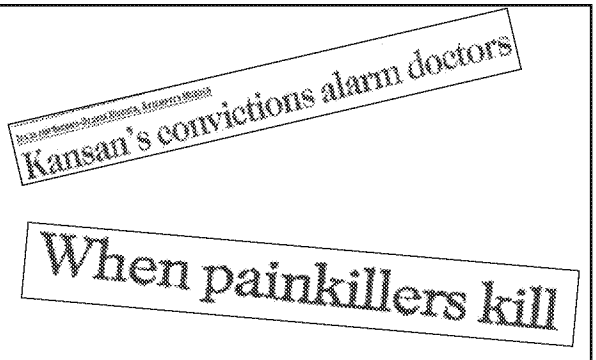
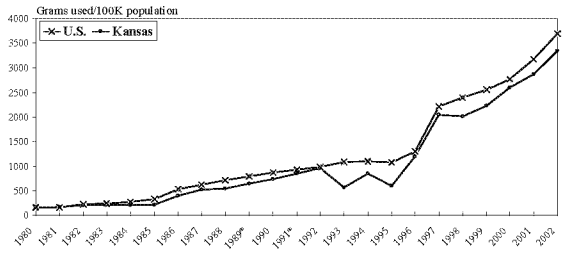


Consumption of Morphine: U.S. vs Kansas, 1980-2002



* 1989 and 1991 data interpolated due to incomplete reporting.
Source: ARCOS, U.S. Drug Enforcement Administration
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2004

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Kansas
(since Narramore)

- Model Guidelines
- Joint Policy Statement
- Nursing Board Policy Statement
- Dissemination/education

Resources available from PPSG

- Literature on pain and regulatory policy
- Evaluation of each state's policies
- Models for change
- Full text data base of all state policies
- Technical assistance

www.medsch.wisc.edu/painpolicy

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Thank you!

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Appropriate Pain Care: Regulatory Environment

Michael A. Moné, JD, FAPhA
Legal and Regulatory Affairs Consultant
April 8, 2005
Boston, Massachusetts

Appropriate Pain Care: Regulatory Environment

- Pain Policy
  - View toward consensus.
  - National Organization statements.
    - FSMB Model Policy
    - NABP Model Rules
    - Professional Associations
    - Public Interest/Advocacy Groups
  - Authority
  - Leadership

Appropriate Pain Care: Regulatory Environment

- "Steal what works."
- Adapt what is available.
- Not everything is going to work in each environment, but progress itself is valuable.
- Are there good models out there?
  - Kentucky KASPER
    - How it started
    - How it works

Appropriate Pain Care: Regulatory Environment

- Board of Pharmacy Response
  - 6 cases of failure to report.
  - Facilitates in identifying potential problems.
  - Provides opportunity for education.
  - Shortens time to investigate.
  - Shortens time to conclusion of prosecution.
  - Provides an opportunity for groups to come together to address societal problems.

Appropriate Pain Care: Regulatory Environment

- Physician/Pharmacist Dialogue
  - Have you attended the Board Meeting of the other Profession?
  - Do you obtain copies of the minutes of the other Board's meeting?
  - Is it discussed at the Board Meeting?
  - Differences in agencies affect the dialogue.
  - Are the professional associations communicating?
  - Will Boards accept mantle of thought leaders?

Appropriate Pain Care: Regulatory Environment

- Physician/Pharmacist Dialogue
  - Movement toward Medication Therapy Management.
  - Closer collaboration in patient care.
  - Decrease in complaints about other profession when "partners in care."
  - Therapeutic choices are easier to understand when there is a foundation of cooperation.
  - Extra data collection about the patient.
    - Over and Under reporting of quality of life.

Appropriate Pain Care: Regulatory Environment

- Contracts with patients
  - Has the pharmacist been informed?
  - Does the pharmacist have a copy?
  - Is the pharmacist a recognized partner in monitoring?
  - Has the pharmacist been empowered to make decisions?
  - Fax machine, e-mail, technology…
  - Need to know…

Appropriate Pain Care: Regulatory Environment

- Professionalism
  - Duty analysis
  - Foster cooperation
  - Diagnosis code on prescriptions
  - Identify purpose for use
- Communication
  - The system we have is aptly described as a failure to communicate.

Appropriate Pain Care: Regulatory Environment

- Perception
  - Perception is that Board of Pharmacy does more and is tougher on its licensees than the Board of Medicine.
  - Perception is reality.
  - What is being done to demonstrate cooperation?
  - Have we achieved balance?

Appropriate Pain Care: Regulatory Environment

- Not only must the practicing profession communicate, Boards must communicate so that mixed signals do not go out to the professions.
- Joint policy statements demonstrate commitment of the respective Boards to the outcomes identified in the policy statement.
- Fundamentally a quest for certainty.
- Risk averse professions.

Appropriate Pain Care: Regulatory Environment

- Others who must be included:
  - Local DEA
  - State Mental Health Programs
  - State Prosecutors
  - Legislators
  - Public Advocacy Groups
  - Defense Attorneys

Appropriate Pain Care: Regulatory Environment

- Rationality
  - Reasonable person standard
- Balance
- Consistency
  - Same message from all Boards
- Accountability
- Liability
  - The great fear.

Appropriate Pain Care: Regulatory Environment

- **Resources:**
  - FSMB
    - www.fsmb.org
  - NABP
    - www.nabp.net
  - Professional Association policies.
  - DEA
    - www.usdoj.gov/dea
  - Academic centers, e.g. University of Wisconsin
    - www.medsch.wisc.edu/painpolicy

Appropriate Pain Care: Regulatory Environment

- Thank you

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U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Balance & Fairness in Regulatory Enforcement

An Informational Briefing Prepared for:

Federation of State Medical Boards

-

Presented by:

Patricia M. Good,

Chief, Liaison & Policy Section

Office of Diversion Control

Office of Diversion Control

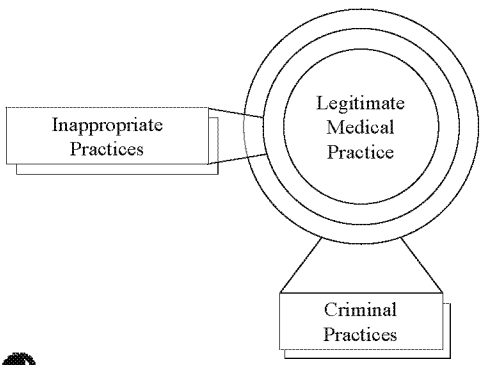
Regulatory Fairness

"Doctors acting in good faith and in accordance with established medical norms should remain confident in their ability to prescribe appropriate pain medications."

- Karen P. Tandy,
Administrator,
Drug Enforcement Administration

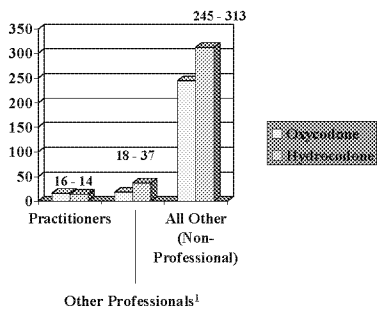
Office of Diversion Control

Regulatory Fairness



Office of Diversion Control

Arrests for FY 2004 by Drug Type



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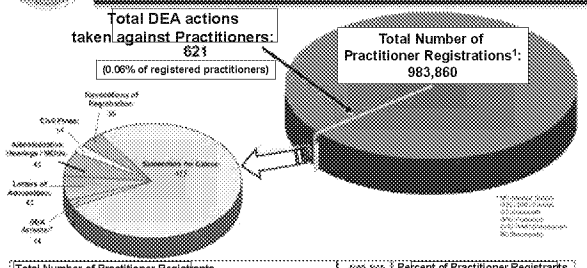
[1] Other Professionals include Pharmacists and other DEA registrants

DEA Actions Taken Against Practitioners – FY 2004



Total Number of Practitioner Registrants	983,860	Percent of Practitioner Registrants
Criminal / Complaint Invest. of Practitioners initiated in FY 2004	733	0.07496%
Total DEA Actions Taken Against Practitioners in FY 2004	621	0.06312%
Practitioners Arrested by DEA in FY 2004 [2] *	14	0.00143%

*

Questions?

Office of Diversion Control

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Special Article

Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change

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Abstract

Physicians' concerns about regulatory scrutiny and the possibility of unwarranted investigation by regulatory agencies negatively affect their prescribing of opioid analgesics to treat pain. Indeed, some state medical boards have rejected prescribing practices that are considered acceptable by today's standards. This article describes a ten-year program of research, education, and policy development implemented by the Pain & Policy Studies Group aimed at updating and clarifying state medical board policies on the use of opioid analgesics to treat pain, including cancer and chronic noncancer pain. Following surveys of medical board members and educational workshops, state medical board policies began an initial period of change, drawing on guidelines from other states, particularly in California. The next phase of policy development was marked by the introduction of Model Guidelines by the Federation of State Medical Boards of the U.S. The Model Guidelines address professional standards for the appropriate prescribing of opioid analgesics for pain management, as well as physicians' fears of regulatory scrutiny. Although most state medical boards have adopted regulations, guidelines, or policy statements relating to controlled substances and pain management, to date ten boards have adopted the Model Guidelines, while ten more have adopted the Model Guidelines in part. Further actions are recommended so that state medical boards can address inadequate pain management and physician concerns about regulatory scrutiny. J Pain Symptom Manage 2002;23:138–147. © *U.S Cancer Pain Relief Committee, 2002.*

Key Words

Medical boards, pain policy, chronic pain, cancer pain, opioids

Introduction

There are many safe and effective treatments for pain, both pharmacologic and non-pharmacologic. Clinical practice guidelines, as well as other authoritative sources, emphasize that opioid analgesics are essential for the treatment of moderate to severe pain, especially acute pain[1,2] and cancer pain.[3–4] In addition, there is a growing consensus that opioids can be appropriate for certain patients with chronic noncancer pain if there is proper evaluation and monitoring of pain relief and functional out-

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comes.[5–7] Despite the availability of such treatments, inadequate management of pain has been found in patients with a variety of diagnoses and conditions[8–12] and in a variety of health-care settings.[13–19]

It is well-documented that many factors, or barriers contribute to inadequate treatment of pain; among these are physicians' fears of being investigated for prescribing opioids.[20–24] Studies have demonstrated that physicians underprescribe opioid analgesics out of fear of state board disciplinary action, even though prescribing opioids for pain management is legitimate if done in the course of professional practice. Apprehension on the part of physicians seems warranted by evidence from a 1991 survey indicating that some members of state medical boards, the organizations that license and discipline physicians, appear to have attitudes and beliefs that conflict with the use of opioids for treatment of pain.[25] These attitudes may be reflected in the policies issued by a state medical board, as well as in a board's enforcement procedures. Indeed, some board policies have contained statements and recommendations that discourage the use of opioid analgesics for pain management.

There is a need for state medical boards to adopt policies that encourage adequate pain management and dispel physicians' fears of being disciplined, in keeping with accepted medical practice. Adoption and dissemination of such policies can play an important role in modifying physicians' knowledge, beliefs, and practices concerning the treatment of pain with opioid analgesics. It is important to note that national organizations such as the American Medical Association[26] and the Federation of State Medical Boards in the United States (FSMB)[27] have advocated a non-legislative approach to promoting the use of controlled substances for pain management, which is the focus of this paper. In addition, some state statutes may hinder appropriate pain management by containing additional restrictions or requirements on prescribing opioid analgesics,[28–29] superceding the authority of state medical boards to regulate medical practice.[27]

Over the last decade, a program of research, education and policy evaluation was undertaken by the Pain Policy Studies Group (PPSG) with state medical boards and national pain associations to address physicians concerns about regulatory scrutiny. The program was developed in several stages, beginning with a national survey of state medical board members and followed by educational workshops for board members, evaluation of medical board policies, and technical assistance to develop model state medical-regulatory guidelines for the use of controlled substances in pain management. Taken together, these efforts demonstrate that regulatory agencies are making efforts to recognize the importance of pain management with opioids, for cancer and non-cancer conditions.

Physician Concern About Regulatory Scrutiny

A 1990 survey of oncologists studied the reasons for inadequate cancer pain management and found that 18% rated excessive regulation of analgesics as one of the top four barriers.[30] Indeed, oncologists in several states had been investigated and prosecuted for prescribing opioids to cancer patients (who were by then deceased). Eventually the charges were dismissed, but these events reached the news media, including being described in a cancer journal.[31]

A 1991 survey of Wisconsin physicians found that more than half would at least occasionally reduce dose, quantity or refills, or prescribe a drug in a lower schedule due to fear of regulatory scrutiny.[32] These physicians' concerns about investigation were least when opioids were prescribed for acute pain, but increased if prescribing was for chronic cancer pain; concern was greatest if prescribing was for chronic pain not related to cancer, or for patients with a history of drug abuse.

In that same year, 40% of surveyed physician-members of the American Pain Society (APS) said that concerns about regulatory scrutiny, rather than medical reasons, led them to avoid prescribing opioids for chronic non-cancer pain patients.[33] In a national survey of physicians, some respondents reported that regulatory pressure restricted their use of opioids for patients with chronic non-cancer pain.[23] Indeed, the use of opioid analgesics for chronic non-cancer pain has been controversial[6,34,35] and actively discouraged by some in both the pain and regulatory communities. More recently, clinicians, researchers, and regulators have be-

gun to reexamine the use of opioids for chronic non-cancer pain, including treatment efficacy, potential of adverse pharmacologic effects, and abuse and addiction liability, concluding that there is a role for opioids in carefully-selected patient populations.[5–7,36,37]

Research and Education with State Medical Boards

In response to these findings, in 1991 the PPSG surveyed all the members of state medical boards to assess whether board members' knowledge and attitudes could pose a threat to physicians who prescribe opioids for management of chronic cancer and non-cancer pain.[25] With the cooperation of the FSMB, a confidential pre-tested questionnaire was mailed to all 627 state medical board members in the U.S. A 50% response rate was achieved. Respondents represented 49 states, with a mean of six respondents per state. Physicians, public members, and other health-care practitioners were surveyed; 79% of the respondents were physicians and 15% were public members.

To directly address the validity of physicians' fears of regulatory scrutiny, board members were asked their opinions about the legality and medical acceptability of prescribing opioids for more than several months to patients with different diagnoses, including a patient with chronic cancer pain and a patient with chronic non-cancer pain. The respondent could indicate whether the prescribing practice was: (1) lawful and generally acceptable medical practice, (2) lawful but generally not acceptable and should be discouraged, (3) probably a violation of state medical laws or regulations and should be investigated, (4) probably a violation of federal or state controlled substances laws and should be investigated, or (5) that the respondent did not know the legality of extended opioid prescribing. It is important to note that, while federal drug enforcement policy recognizes that the use of opioids for pain including for patients with chronic disorders is lawful, it remains the province of the states to determine what constitutes legitimate medical practice.[21,38,39]

While most respondents agreed that the prescribing of opioids for the cancer patient was legal and generally acceptable medical practice, only 12% were confident in the legality of prescribing for the patient with chronic non-cancer pain; the majority of respondents (77%) would discourage this practice or even investigate it as a violation of law. It is of interest that the median year in which the physician-board members received their medical training was 1961, before pain treatment became a clinical science, before pain relief had become a public health priority, and well before the growing recognition that opioids could be used for patients with chronic non-cancer pain. There were also deficiencies in board members' knowledge about the extent to which cancer pain can be relieved, appropriate pharmacologic treatments for moderate to severe cancer pain, and the meaning and incidence of addiction when opioids are used to manage pain. Public members were more likely to indicate that they did not know the answers to survey items.

The survey results showed a clear need to update medical board members' knowledge about pain management and public policy. The findings were published in the FSMB journal, the *Federation Bulletin*,[25] in order to further a working relationship aimed at education, policy evaluation, and future research with the medical boards. The PPSG initiated a series of seminars for board members, believing that they would want to know about recent developments in pain management, and that they would respond to other physicians' concerns about being investigated for prescribing to treat chronic pain.

The PPSG and the FSMB cosponsored a series of 11 workshops on "Pain Management in a Regulated Environment" between 1994 and 1998. The faculty for all workshops was consistent, and included experts in pharmacology, pain medicine, addiction medicine, and public policy. Workshop content included the extent of the pain problem, the reasons for inadequate management of pain including exaggerated fear of addiction and concerns about regulatory scrutiny, methods for the assessment and treatment of pain, a review of recent advances in the understanding of pain physiology and opioid pharmacology, and the status of federal and state controlled substances and professional practice law, regulations, and medical board guidelines about the use of controlled substances for pain management.[40]

A total of 297 representatives of state medical boards signed up to participate in any one of the 11 one-day workshops; the participants

represented 40 states and approximately 25% of the total board member population.[40] Participants in the workshops included both physician and public members, as well as some investigators, attorneys, and administrative staff. All participants completed a pre-test, post-test, and follow-up survey to evaluate changes in knowledge and attitudes as a result of their involvement in the workshops.[40]

Evaluation of State Medical Board Policy

In the next phase of the program, the quality of state medical board policies was evaluated to better understand the potential for these policies to pose a threat to physicians who prescribe controlled substances for pain management. Medical board policies and guidelines express the attitude of the board regarding controlled substances and pain management. By 1990, few medical boards had adopted policies relevant to controlled substances and the treatment of pain; most of these early policies were eventually superceded by new policies.[28] By 2000, more than half of the state medical boards had adopted pain guidelines (see Fig. 1). The full text for the medical board policy in each state can be found at: http://www.medsch.wisc.edu/painpolicy/matrix.htm.

A team analysis approach[41] with three researchers was used to evaluate guidelines and policy statements that had been adopted in 24 states between 1989 and 1997, the most recent year for which policies were available when this study was begun (see Table 1). Each policy was rated according to several criteria, including whether the guidelines: (1) contained a stated purpose to address concerns about regulatory scrutiny, encourage pain management, and encourage physicians to become knowledgeable about pain management; (2) recognized the medical use of opioids for pain, including chronic non-cancer pain; and (3) recognized that certain restrictions or requirements could interfere with prescribing opioids for pain management.

The raters' evaluations of the items found in each policy were compared to determine the extent of discrepancy, i.e., when raters had different responses. There was an initial agreement of 86% among raters, suggesting high "reproducibility" (p. 17).[42] For each discrepancy, the reasons were determined and a consensus was achieved and recorded. Percentages were calculated to represent the extent that each item was present in each policy.

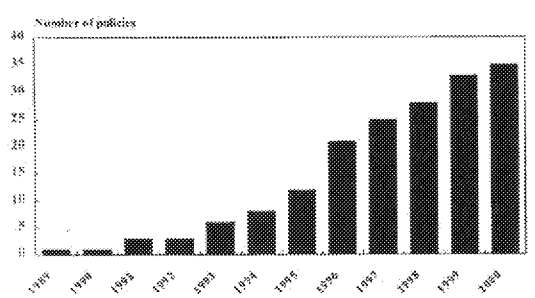

Fig. 1. The cumulative trend in the number of pain management or controlled substances policies adopted by state medical boards in the United States from 1989 to 2000.

Stated Purpose of the Policy

Fifty-four percent of the 24 policies (13 states) recognized physicians' concerns about regulatory scrutiny but only 33% (8 states) actually addressed the concerns by providing guidelines or principles the board uses to distinguish legitimate from questionable prescribing practices. Thirty-eight percent of the guidelines (9 states) included statements that encouraged pain management; 46% (11 states) provided physicians with sources of information about pain management, such as the Agency for Health Care Policy and Research clinical practice guidelines or the consensus statement by the APS and the American Academy of Pain Medicine (AAPM).

Recognition of Medical Uses for Opioids

Thirty-eight percent of the guidelines (9 states) recognized the appropriateness of using opioids for cancer pain; 46% (11 states) recognized that opioids may be used for chronic non-cancer

Table 1
Twenty-Four States Represented in Content Evaluation of Medical Board Policies

Alaska	Massachusetts	Rhode Island
Arizona	Minnesota	Tennessee
California	Montana	Texas
Colorado	New Mexico	Utah
Florida	North Carolina	Vermont
Georgia	Ohio	Washington
Idaho	Oklahoma	West Virginia
Maryland	Oregon	Wyoming

pain. For example, a medical board policy statement from North Carolina stated that:

> It should be understood that the Board recognizes opioids can be an appropriate treatment for chronic pain (p. 2).[43]

Twenty-one percent of the guidelines (5 states) stated the principle that pain management, including the use of opioid analgesics, should be considered a part of quality medical practice. For example, Washington's policy contains a statement that directly addresses this issue:

> Under generally accepted standards of medical practice, opioids may be prescribed for the treatment of acute or chronic pain including chronic pain associated with cancer and other non-cancer conditions (p. 1).[44]

Additional Requirements and Restrictions

Several state medical boards had policies that created potential barriers to pain management because they placed additional and apparently inflexible restrictions on a physician's ability to make an independent medical decision about the use of opioid analgesics that should be based on the physician's expertise and the individual characteristics of the patient. These restrictions fell into two groups: Those that require in *every* case that opioids be used only after other treatments, and those that require consultation with an expert in *every* case involving a patient with a history of substance abuse. Two states (8%) required that other treatments be attempted before opioids are used for chronic non-cancer pain. For example, an Ohio medical board policy statement indicates that treatment of chronic pain with opioid analgesics can begin only when:

> There is documentation that pain cannot be adequately controlled by other treatment methods such as, but not limited to behavior modification, non-narcotic medications, physical therapy, TENS, manipulation, and other forms of recognized treatment (pp. 4–5).[45]

While trials of non-opioid treatments are certainly reasonable, it is unclear how many treatments a physician should require of the patient in order to avoid possible discipline, or what should be done in the case of a patient's need for immediate pain relief. Such requirements may delay pain management, increase the costs of treatment, and marginalize opioids as a treatment of last resort.

Nine guidelines (47%) appeared to mandate consultation with another physician when the patient has a history of substance abuse:

> The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists...(p. 1).[46]

Assessment of patients for a history of substance abuse is very important, but requiring a consultation in every case may not be necessary, especially when the physician is well-trained or an expert. However, the failure to meet this requirement could result in a disciplinary proceeding.

The evaluation of state medical board policies showed that there was a lack of clear and consistent purpose, and considerable variation in policy content across states.[47] Only some policies encouraged better pain management, addressed physicians' concerns about regulatory scrutiny, or clarified the board's view of the role of opioids in pain management.[28] The analysis was presented to the FSMB, which used it to inform a process that was begun to study and improve the content and consistency of state medical board pain policies.

The Development of Model Guidelines for State Medical Boards

In 1997, the FSMB convened a task force of pain, policy, and regulatory experts to develop "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain,"[37] which could be given to all state medical boards for their consideration. A draft was prepared, taking advantage of the PPSG's policy evaluation and incorporating exemplary language from several state medical boards' policies.[48] The FSMB sponsored a public forum to receive comments on the draft from a variety of medical and pain organizations, state medical boards, and patient advocacy groups.[48] A representative of the U.S. Drug Enforcement Administration (DEA) presented a written statement which said in part:

> The guidelines will help physicians comply with acceptable pain management standards and will help DEA and other regulators de-

termine whether such treatment is appropriate under the circumstances. Perhaps most importantly, the guidelines will help ensure patient access to needed controlled substances for pain management (p. 4).[49]

The Model Guidelines contain language that clearly recognizes the medical uses of controlled substances for pain, encourages physicians to provide adequate pain management for all patients, recognizes and addresses fear of regulatory scrutiny, and encourages physicians to update their knowledge about pain management (see Table 2). In addition, the Model Guidelines present guidelines for prescribing controlled substances that are based on the general principles of good medical practice, which include having a bona fide physician-patient relationship, physical examination, diagnosis, treatment plan, informed consent, periodic monitoring, documentation, consultation as needed, and adherence to federal and state laws concerning controlled substances. The Model Guidelines recognize that opioids can be appropriate for pain control even when a person has a history of substance abuse, and recommend the use of a written agreement outlining patient responsibilities and monitoring of medication use. Up-to-date definitions are provided for key terms that are commonly misused, including addiction, tolerance and physical dependence. A relatively new concept, "pseudoaddiction,"[50] is defined in order to draw attention to the importance of distinguishing between patients who request more pain medications because their pain is inadequately managed, and persons who seek drugs for other than legitimate purposes.

The Model Guidelines do not contain unwarranted additional requirements or restrictions. Indeed, they are explicitly flexible:

> Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physicians conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved. (p. 2)[37]

The Model Guidelines were unanimously adopted by the Federation's House of Delegates on May 2, 1998. Subsequently, they were endorsed by the APS and the AAPM.[18] The Model Guidelines represent an emerging consensus among groups representing the perspectives of pain management, regulation, and drug law enforcement about the medical use of controlled substances for the treatment of pain. The intention of the FSMB is that the Model Guidelines be considered and acted upon by all state medical boards.[27] The Model

Table 2
Selected Provisions of the Model Guidelines

- "The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." (p. 1)
- "The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness." (p. 1)
- "Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients." (p. 1)
- "Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substance, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice." (p. 2)
- "The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing." (p. 2)
- "All physicians should become knowledgeable about effective methods of pain treatment. . . Physicians are referred to the U.S. Agency for Health Care [Policy] and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities." (p. 1)

Source: Federation of State Medical Boards of the United States, Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Euless, TX; May 1998.

Guidelines are available on the FSMB Web site at http://www.fsmb.org. The Model Guidelines, endorsements of the Model Guidelines, as well as all state medical board policies and state laws governing the use of controlled substances for pain management, are available on the PPSG Web site at http://www.medsch.wisc.edu/painpolicy/matrix.htm.

Discussion

That physicians fear they will be investigated for writing excessive opioid prescriptions has been described as an "unwritten doctrine" (p. 257).[51] Although opioid analgesics have been regarded as the mainstay of treatment for pain related to surgery and trauma for many years, national encouragement of their use for cancer pain did not occur until more recently.[1–4] There is a growing consensus supporting the use of opioids in chronic non-cancer pain.[5,37] These changes, along with the advent of new information about pain physiology, opioid pharmacology, and revised conceptions of addiction and dependence, represent new knowledge that needs to be incorporated into medical education and practice.[52] It is essential that state medical policies adapt to these changes.

The Model Guidelines provide a carefully considered policy framework that can be used by state medical boards to accomplish this goal. However, many state medical boards have yet to adopt the new guidelines, as recommended by the FSMB.[27] Since May of 1998, ten state medical boards have adopted policies that are substantially the same as the Model Guidelines: Alabama, Florida, Kansas, Minnesota, Nebraska, Nevada, Pennsylvania, South Carolina, South Dakota, and Utah. In addition, another ten state medical boards have issued policies that use the Model Guidelines in part: Arizona, Kentucky, Louisiana, Maine, Missouri, New Hampshire, New York, Oklahoma, Tennessee, and West Virginia. Most of the medical boards from these states had at least one member participate in the workshops on "Pain Management in a Regulated Environment." Apparently, the workshops provided not only a rationale but an impetus for medical boards to develop policy to encourage pain management and to allay physicians' fears about regulatory scrutiny. Identifying all the catalysts for policy development by state medical boards will require further study.

Conclusions and Recommendations

Successful elimination of physician fear of regulatory scrutiny will depend in part on achieving more balanced controlled substances policies in each state (i.e., policies that aim not only to prevent drug abuse but also acknowledge the important medical uses of controlled substances, in particular the opioid analgesics).[29,53] The purpose is not to advocate the use of opioids for all pain, but to encourage effective pain management, including the use of opioids when appropriate.

We recommend that all state medical boards adopt guidelines or policy statements (rather than statutes) on the use of controlled substances for pain management, and ensure that investigation and discipline of physicians is consistent with board policy and does not interfere with pain management. New state board guidelines should be based on the FSMB Model Guidelines. They should be disseminated to all licensed physicians, and publicized through the boards' Web sites, newsletters, and press releases. In addition, we urge that medical boards cooperate with state boards of pharmacy and nursing to coordinate and establish policies that reflect a consensus of health-care professionals, as has been done in Washington, North Carolina, West Virginia, and Kansas. Alternatively, physicians could work with their medical society to develop pain management policies, which could then be endorsed by the state medical board.

We encourage state medical societies to organize educational programs for physicians that address pain management, regulatory requirements, medical board policies, and concerns about regulatory scrutiny. Medical boards can participate in such efforts, communicating directly with physicians and addressing their perceptions of risk.

Despite dissemination of guidelines to licensees, practitioners often remain unaware of new policies in their state.[48,54] Overcoming this communication gap requires attention to effective communication strategies. The North Carolina medical board has made great effort to communicate its pain guidelines, and has sponsored educational programs about pain

and end-of-life care for both the public and professionals. Most medical boards have little in the way of educational resources and will need support. One strategy has been employed by the Alabama Board of Medical Examiners through joint sponsorship of educational events with the state medical society. Approximately 75% of medical boards have sponsored Web sites and newsletters; these can be used to inform licensed practitioners of the board's policy to encourage pain management.

If the collective efforts of the pain management and regulatory communities do not make significant progress to eliminate fears of regulatory scrutiny, frustration with physicians who do not provide adequate pain management will mount and may lead to policies that penalize *inadequate* pain management. Such policies have already been discussed by the Institute of Medicine and state medical boards.[22,52] Indeed, the Oregon Board of Medical Examiners disciplined a physician for inadequate pain management.[53] In lieu of license revocation, the Oregon Board required the physician to participate in an intensive educational curriculum about pain management.

We believe that education, not discipline, should be the cornerstone of efforts to improve pain management. However, it is axiomatic that if pain management is to be an expected part of quality medical practice, then substandard pain management practice must be subject to review and corrective action as in any other area of medical practice.

The trends in state medical board policies reported here are a reflection of increasing concern about inadequate pain management. Making real improvements in pain management will require the proactive efforts of many organizations. The contribution of state medical boards and other regulatory agencies is a welcome addition.

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Improving State Medical Board Policies: Influence of a Model

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Despite advances in medical knowledge regarding pain management, pain continues to be significantly undertreated in the United States. There are many drug and nondrug treatments, but the use of controlled substances, particularly the opioid analgesics, is universally accepted for the treatment of pain from cancer. Although opioid analgesics are safe and effective in treating chronic pain, there is continued research and discussion about patient selection and long-term effects. A number of barriers in the health care and drug regulatory systems account for the gap between what is known about pain management and what is practiced.[1] Among the barriers are physicians' fears of being disciplined by state regulatory boards for inappropriate prescribing.[2]

State medical boards are in a unique position not only to address physicians' concerns about being investigated, but also to encourage pain management. Prior to 1989, a few state medical boards had policies relating to controlled substances or pain. Subsequently, state medical boards began adopting policies regarding the prescribing of opioids for the treatment of pain; many of these specifically addressed physicians' fear of regulatory scrutiny. Since 1989, forty-one state medical boards have adopted such policies, including regulations, guidelines, and policy statements (see Figure 1). "Regulations" are official rules issued by the medical board pursuant to legislative authority; regulations have the force of law and establish the boundaries of acceptable conduct for licensed physicians. "Guidelines" are official statements that define the parameters of medical practice as viewed by the board. "Policy statements" are position statements that address matters of concern to the board and may clarify the board's expectations. While guidelines and policy statements may not have binding legal force, they do communicate the board's attitude toward certain medical practices.

Regulations, guidelines, and policy statements reflect the knowledge and attitudes of the board members who develop them, suggesting that the content of board policies may change over time, just as changes occur in board members' understanding of the developments in medical knowledge. For example, in September 1987[3] and August 1989,[4] the Washington State Disciplinary Board issued policy statements that specifically discouraged the use of opioid analgesics for the treatment of pain. A subsequent guideline in 1992 stated that chronic pain is "best not treated with opioids."[5] Four years later, after reexamining the role of opioids in chronic pain, the board stated:

> opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline [by the boards].... Opioid analgesics can be useful in the treatment of patients with intractable non-cancer pain....[6]

Efforts to revise or develop state medical board policies initially were modeled after California's guidelines. In 1994, the Medical Board of California collaborated with experts in pain policy to draft guidelines on the use of opioids for pain treatment.[7] The guidelines and accompanying policy statement recognized that opioids are a part of professional practice, encouraged pain management, and addressed physicians' fears of regulatory scrutiny. Several state medical boards, including in Arizona, Colorado, Maryland, and Minnesota, adopted similar policies, acknowledging that California's policy was used as a model.

In 1997, recognizing the need for more consistency in state pain policies, the Federation of State Medical Boards

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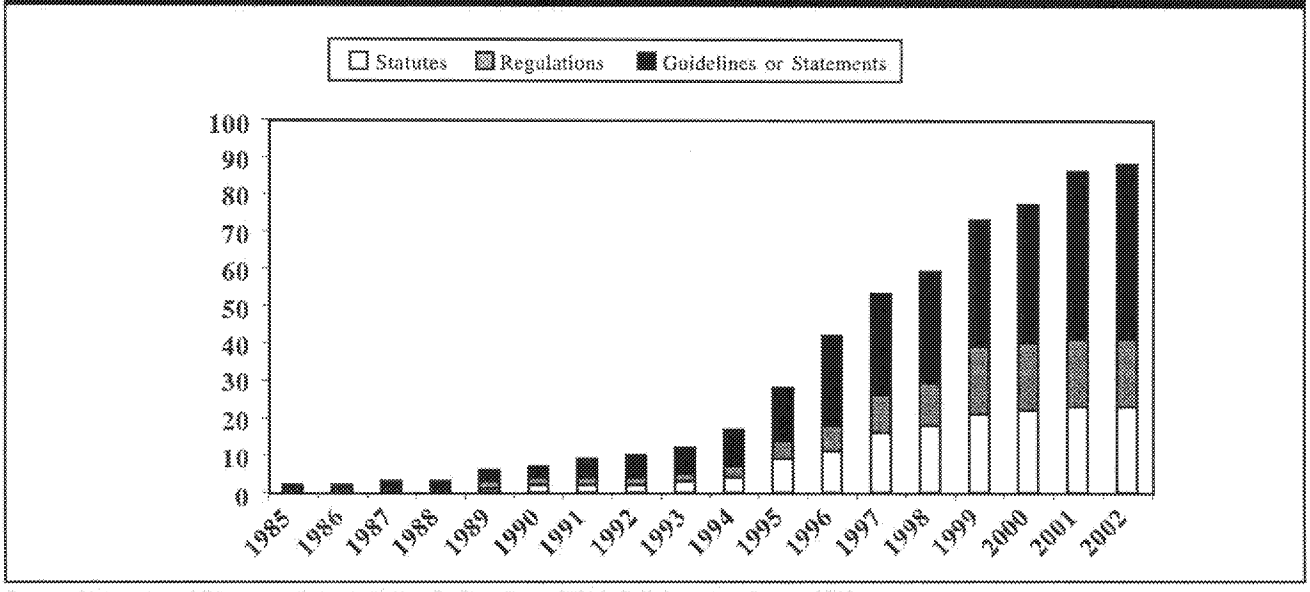
FIGURE 1. CUMULATIVE NUMBER OF STATE PAIN POLICIES, 1985–2002.



Source: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2002.

(FSMB) convened a workgroup of experts to draft a model guideline for the medical use of controlled substances in pain management. Drafting of the model was informed by a preliminary Pain & Policy Studies Group (PPSG) study that showed substantial variation in the content of existing state medical board pain policies. In May 1998, the FSMB adopted the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.[8] The FSMB then sent the Model Guidelines to the state medical boards and asked them to consider adopting the policy.[9]

To date, twenty-two states have adopted policies using all or part of the Model Guidelines.[10] Two more states (Massachusetts and Minnesota) have endorsed rather than adopted the Model Guidelines. However, there has been no research to determine precisely how state medical board policies may have changed and to determine the influence of the FSMB Model Guidelines.

Three research aims guide this study. First, we evaluated the influence of the Model Guidelines on medical board policies adopted after May 1998. Second, we evaluated the differences between policies adopted before the Model Guidelines with those adopted subsequently. Third, we evaluated differences according to the type of policy — whether regulations, guidelines, or policy statements — independent of when they were developed.

METHODOLOGY

We collected and evaluated all state medical board regulations, guidelines, and policy statements related to the use of controlled substances for pain management. Excluded were statutes pertaining to the treatment of pain, such as Intractable Pain Treatment Acts (IPTAs), and court cases relating to civil or administrative law, because these are not state medical board policies. Only provisions relating directly to medical practice were considered; we did not consider provisions pertaining to reimbursement, controlled substances scheduling, workers' compensation, continuing medical education, Internet prescribing, hospice care, or advance directives, including power-of-attorney and living wills.

The policies were obtained from several sources, including updated PPSG hard copy files and LexisNexis, an electronic legal database. The policies analyzed for this study were adopted between January 1985 and December 2001, and are listed in Table 1.

Over a two-week period, three PPSG policy analysts conducted independent evaluations of each policy using a set of seventeen criteria that had been developed to evaluate federal and state policies according to the central principle of balance.[11] The principle of *balance* provided a framework for developing specific evaluation criteria. In summary, this principle recognizes that governmental policy should be aimed at preventing abuse of narcotic drugs, but also at ensuring availability of opioids, which are essential for pain relief; efforts to prevent drug abuse should not interfere in the legitimate medical use of opioids for patient care. The individual criteria are supported by legal and medical authoritative sources, and are intended to identify key elements of governmental policies for the use of controlled substances in pain management to determine if they are balanced.

The criteria are divided into two groups (see Table 2). The two groups are (1) "positive" criteria, which identify policy language that has the potential to enhance pain man-

TABLE 1. STATE MEDICAL BOARD POLICIES EVALUATED.

STATE	POLICY TYPE	YEAR ADOPTED	TITLE OR REFERENCE NUMBER
Alabama	Regulation	1995	Ala. Admin. Code r. 540-X-4-.08
Alabama	Regulation	2000	Ala. Admin. Code r. 540-X-4-.08 (amended)
Arizona	Guideline	1997	Guidelines for Prescribing Controlled Substances
Arizona	Guideline	1999	Use of Controlled Substances for the Treatment of Chronic Pain
Arkansas	Regulation	1997	Regulation 2(6)
Arkansas	Regulation	1998	Regulation 2(6)
California	Guideline	1985	Guidelines for Prescribing Controlled Substances for Chronic Conditions
California	Guideline	1994	Guidelines for Prescribing Controlled Substances for Intractable Pain
California	Policy Statement	1994	A Statement by the Medical Board
Colorado	Guideline	1996	Guidelines for Prescribing Controlled Substances for Intractable Pain
Florida	Guideline	1996	Management of Pain Using Dangerous Drugs and Controlled Substances
Florida	Regulation	1999	Fla. Admin. Code Ann. r. 64B8-9.013
Georgia	Guideline	1991	Management of Prescribing with Emphasis on Addictive or Dependence-Producing Drugs
Idaho	Guideline	1995	Prescribing Opioids for Chronic Pain
Iowa	Regulation	1997	653 Iowa Admin. Code 13.2 (148,150,150A,272C)
Kansas	Guideline	1998	Guidelines for the Use of Controlled Substances for the Treatment of Pain
Kentucky	Guideline	1996	Guidelines for Prescribing Controlled Substances
Kentucky	Guideline	2001	Model Guidelines for the Use of Controlled Substances in Pain Treatment
Louisiana	Regulation	1997	La. Admin. Code 46:XLV.6923 (*et seq.*)
Louisiana	Regulation	2000	La. Admin. Code 46:XLV.6915 (*et seq.*)
Maine	Regulation	1999	Code Me. R. 02-373-011
Maryland	Guideline	1996	Prescribing Controlled Substances
Massachusetts	Guideline	1989	General Guidelines for the Use of Narcotic Analgesics in Chronic Pain
Massachusetts	Guideline	2001	*No title*
Massachusetts	Guideline	2001	Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (adopted by reference)
Minnesota	Guideline	1988	Cancer Pain Management Information
Minnesota	Guideline	1995	The Common Denominator and Common Sense
Minnesota	Policy Statement	2000	Pain Management: A Patient's Right to Adequate Pain Control
Mississippi	Policy Statement	1997	Pain, Pain Management and Mississippi Medical Board of State Licensure Scrutiny
Mississippi	Regulation	1999	Miss. Code Ann. § 50-013-022

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